California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA

Legislation and Regulation Committee

Contact Person: Virginia Herold
(916) 574-7911

Date: January 7, 2009
Time: 1:00 p.m. – 3:30 p.m.

Place: Samuel Greenberg Board Meeting Room
Los Angeles International Airport
1 World Way
Los Angeles, CA 90045

(Directions Attached)

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tina Thomas at (916) 574-7941, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. A quorum of the Board members who are not on the committee may attend the meeting as observers, but may not participate or vote. Action may be taken by the committee on any item listed on this agenda.

MEETING AGENDA

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order **1 p.m.**

A. Regulation Report and Action (*Note: CCR as used below means California Code of Regulations)*

1. *Board Approved Regulations – Undergoing Administrative Review*
   Amend Title 16 CCR Section 1760 – Disciplinary Guidelines

2. *Board Approved Regulations – Previously Noticed (Not for Discussion at this Committee Meeting)*
   a. Title 16 CCR Repeal 1716.1 and 1716.2, Amend and Adopt Sections 1751-1751.8. and Adopt Sections 1735-1735.8 – Pharmacies that Compound
   b. Title 16 CCR Amend 1773 and Adopt 1773.5 – Ethics Course

3. *Board Approved Regulations – Awaiting Notice*
   a. Title 16 CCR section 1715 and 1784 – Section 100 Changes to Update the Self Assessment Forms for Pharmacies and Wholesalers
   b. Title 16 CCR Section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer
   c. Title 16 CCR Section 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

d. Title 16 CCR sections 1721 and 1723.1 – Dishonest conduct during a Pharmacist's Licensure Examination/Confidentiality

4. *Proposed Regulation Language for Board Discussion and Possible Action*
   a. *Amend Title 16 CCR section 1715 – Self-Assessment Forms for Community and Inpatient Pharmacies*
   b. Amend Title 16 CCR section 1784 – Self-Assessment Form for Wholesalers

5. *Regulations Under Development*
   a. Title 16 CCR section 1780 – Update the USP Standards Reference Material
   b. Title 16 CCR section 1732.2 – Continuing Education for Competency Committee Members

B. Legislative Report

1. *Legislation Sponsored by the Board of Pharmacy*
   a. Reintroduction of 2008 Omnibus Provisions
   b. Omnibus Provisions for 2009
      (1) Disposal of Sharps
   c. Immunization Proposal – Amendment to Business and Professions Code 4052 and Adoption of 4052.8
   d. Elements of a Prescription Label – Amendment to Business and Professions Code section 4076

2. *Legislative Proposal Regarding Return of Medicine to Reverse Distributors*

3. *Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction*
   a. AB 67 (Nava) – Pharmacy Patient Protection Action of 2008
   b. SB 26 (Simitian) – Home-Generated Pharmaceutical Waste
   c. Additional California Legislation Introduced After 12/19/08

C. Public Comment for Items Not on the Agenda*

**(Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Adjournment **3:30 p.m.**

Adjournment time is approximate

Meeting materials will be available from the board's Web site by January 5, 2008

Detailed Directions to the Meeting Location:

The address for the meeting is:
Samuel Greenberg Board Room.
1 World Way
Los Angeles, California 90045

If driving:

Enter off of Century Boulevard. Follow the signs to the "Arrival" area of LAX from Century Boulevard. Stay in the left lane while entering LAX.

To the left will be an off ramp with a sign that will direct you to the Administration Building and parking. At the bottom of the off ramp is a stop sign (the building that the meeting will be held is directly in from of you). Turn right at the stop sign and go about 50 feet to the parking lot that will then be in front of you after the turn. If the gate is down, push the button and tell the guard that your are there for the meeting in the Board Room. The gate will open and you can park anywhere in the lot except where it is reserved for fleet vehicles (that is only about 4 spaces).

If flying:

The administration Building is just east by about 100 yards from Terminal 1 where Southwest lands/takes off at LAX

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Pending Administrative Review

At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR 1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. While the department did approve this regulation, State and Consumer Services Agency is concerned about the optional language relating to automatic revocation when a probationer fails to submit cost recovery as mandated. As a result it is being brought back to the board for further consideration.

To allow the board to continue to pursue the regulation change and obtain agency approval that will be required to move forward with the regulation, the board will need to either withdraw the rulemaking and begin over, or seek a 15-day notice removing this specific term. Either action will require a vote from the full board at the January 2009 Board Meeting to proceed.

Below is the term in question. The objection raised is to the "Option" included.

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

***Option:** If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.*

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Previously Noticed

The below items are not for discussion by the committee.

1. Proposed Repeal of 16 CCR §§ 1716.1 and 1716.2 and amendment to 16 CCR § 1751-1751.8 and adoption of 16 CCR §§1735-1735.8

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing. The subcommittee will be providing recommendations for consideration and action by the board at the January 2009 Board Meeting.

2. Proposed Amendment to 16 CCR §1773 and adoption of 16 CCR §1773.5 – Ethics Course.

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal

studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

The 15-day comment period is over and no additional comments were received. Board staff will begin compiling the rulemaking and will submit it to the department during the first quarter of 2009.

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Notice

1. Proposed Amendment to 16 CCR §1715 and 16 CCR §1784 - Section 100 Changes to Update the Self Assessment Forms for Pharmacies and Wholesalers

Section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. Section 1784 establishes the requirement for the designated representative-in-charge of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. These self-assessment forms are designed to assist pharmacies and wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the pharmacy inspection process more meaningful and provides relevant information to pharmacies and their PIC.

The law requires that the self-assessment form be completed by July 1 of every odd numbered year as well as whenever a change in the pharmacist-in-charge or designated representative-in-charge occurs.

As these forms are incorporated by reference in section 1715 and section 1784 respectively, the board must pursue a regulation change to require use of the new form.

At the October 2008 Board meeting, the board voted to pursue section 100 changes to update the forms that are incorporated by reference. Following are copies of the revised regulation sections as well as the self-assessment forms. Board staff will be pursuing the section 100 changes the first quarter of 2009 to ensure approval in advance of the July 1, 2009 completion date.

2. Proposed Addition to 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

A copy of the draft language and form is provided, however board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

3. Proposed Adoption of 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

At the July 2007 Board Meeting, the board voted to move this proposal.

Following is a copy of the language as approved by the board.

4. Proposed Amendment to 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR 1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Following is a copy of the language as approved by the board.

BOARD OF PHARMACY
Specific Language to amend section 1715

Amend Section 1715 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(c) The components of this assessment shall be on Form 17M-13 (Rev ~~10/07~~ 10/08) entitled "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment (or Form 17M-14 (Rev ~~10/07~~ 10/08) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4305, 4330, 4332 and 4333, Business and Professions Code.

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COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of t~~T~~he California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
(Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____
4. _____ RPH # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
6. _____ INT # _____ Exp. Date: _____
7. _____ INT # _____ Exp. Date: _____
8. _____ INT # _____ Exp. Date: _____
9. _____ TCH # _____ Exp. Date: _____
10. _____ TCH # _____ Exp. Date: _____
11. _____ TCH # _____ Exp. Date: _____
12. _____ TCH # _____ Exp. Date: _____
13. _____ TCH # _____ Exp. Date: _____
14. _____ TCH # _____ Exp. Date: _____
15. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes No N/A

☐☐☐ The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)

☐☐☐ The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)

☐☐☐ The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)

☐☐☐ The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ The pharmacy has a readily accessible restroom. (CCR 1714)

☐☐☐ Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)

☐☐☐ Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

☐☐☐ Does the pharmacy compound sterile injectable drugs?
(If yes, complete section 23 – "Compounding Sterile Injectable Drugs".)

☐☐☐ The pharmacy has procedures in place for taking action to protect the public when a licensed individual employerd by or with the pharmacy is impaired to the extent that it affects his or her ability to practice safely. (B&PC 4104[a])

Yes No N/A

☐☐☐ The pharmacy reports to the board information on any licensed individual any admission by the individual affecting his or her ability to practice safely, and admission of theft, diversion or self-use, evidence documenting the behavior as well as any terminations that result from the behavior. (B&PC 4104)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Delivery of Drugs

Yes No N/A

☐☐☐ Dangerous drugs and dangerous devices are only delivered to the licensed premise, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(a))

☐☐☐ A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);

Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);

The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);

The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and

The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Drug Stock

Yes No N/A

☐☐☐ The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22CCR 70263[q], CCR 1714[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

☐☐☐ The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ Is the PIC in charge of another pharmacy?

☐☐☐ If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)

☐☐☐ Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Duties of a Pharmacist

Yes No N/A

☐☐☐ The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are per formed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))

☐☐☐ The pharmacist as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures, ordering drug therapy related laboratory tests, administering drugs or biologicals by injection, adjusting the drug regimen of a patient, and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

Yes No N/A

☐☐☐ The pharmacist dispenses emergency contraceptive pursuant to statewide protocol found in 16 CCR 1746.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise two interns at any one time. (B&PC 4114, 4023.5, CCR 1726)

☐☐☐ All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

☐☐☐ The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

Yes No N/A

☐☐☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACY PRACTICE

9. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ Pharmacists provide oral consultation (B&PC 4052[a][7], CCR 1707.2):

whenever the prescription drug has not been previously dispensed to the patient;

whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;

upon request; and

whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

☐☐☐ The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

Yes No N/A

☐☐☐ If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

10. Prescription Requirements

Yes No N/A

☐☐☐ Prescriptions are complete with all the required information. (B&PC 4040, 4070)

☐☐☐ Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direction supervision of a pharmacist. (B&PC 4070, CCR 1717)

☐☐☐ If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

☐☐☐ If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

☐☐☐ The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

☐☐☐ Facsimile prescriptions are received only from prescriber's office. (B&PC 4040[c])

☐☐☐ Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

☐☐☐ With the exception of those prescriptions written under H & S 11159.2, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&S 11164[a])

☐☐☐ All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&S 11164[a] [1] , 11120[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

11. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

Yes No N/A

☐☐☐ Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

☐☐☐ Generic substitution is communicated to the patient. (B&PC 4073)

☐☐☐ If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)

☐☐☐ The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

☐☐☐ The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership,

☐☐☐ The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

☐☐☐ Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

12. Refill Authorization

Yes No N/A

☐☐☐ Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

Yes No N/A

☐☐☐ Refills are documented. (CCR 1717)

☐☐☐ Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)

☐☐☐ Refills for Schedule II controlled substances are prohibited. (H&S 11200)

☐☐☐ Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (H&S 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR1711[c][2][A], 1711[c][3]

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ The record for quality assurance review for a medication error contains: (CCR 1711[e])

Date, location, and participants in the quality assurance review;

Pertinent data and other information related to the medication error(s) reviewed;

Findings and determinations; and

Recommended changes to pharmacy policy, procedure, systems or processes, if any.

Yes No N/A

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐☐☐ Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&S 11153)

☐☐☐ Even after conferring with the prescriber, the pharmacist does not dispenses a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Prescription Transfer

Yes No N/A

☐☐☐ Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717[f][1-6])

☐☐☐ Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

☐☐☐ For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

☐☐☐ For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[f], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

16. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐☐☐ If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

17. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

Prescription records (CCR 4081[a])

Purchase Invoices for all prescription drugs (4081[b])

Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)

U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)

Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
Record documenting return of drugs to wholesaler or manufacturer (~~CCR~~ B&PC 4081)

Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

☐☐☐ Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4140, 4149)

Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;

Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

The sale of 10 or fewer hypodermic needles or syringes at any one time to a person 18 or older only if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145)

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

18. DEA Controlled Substances Inventory

Inventory:
Is completed biennially (every two years). Date completed: _____ (21CFR 1304.11[b])

☐☐☐ Schedule II inventory is separate from Schedule 111, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

☐☐☐ Is available for inspection for three years. (CCR 1718)

☐☐☐ Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (CFR 1304.04[h])

☐☐☐ Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

~~Yes No N/A~~

☐☐☐ Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21CFR 1304.04)

Yes No N/A

☐☐☐ U.S. Official Order Form (DEA Form-222) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form-222. (21CFR 1305.03, 1305.12)

☐☐☐ When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form-222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

☐☐☐ When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form-222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22,1988] 503. B&PC 4160)

☐☐☐ When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

☐☐☐ The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ All Schedule II through IV controlled substance dispensing data successfully transmitted to CURES weekly. (H&SC 11165[d])

CORRECTIVE ACTION OR ACTION PLAN:

_____

19. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ A faxed prescription for a Schedule II controlled substance is dispensed after the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ An oral prescription for a schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only after the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form. The licensed facility provides the pharmacy with a copy of the prescriber signed order when available. (21 CFR 1306.11[f], H&SC 11167.5)

☐☐☐ An electronically transmitted order for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy's design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5

☐☐☐ If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it ~~must be~~is filled within 72 hours. (CFR 1306.13[a])

☐☐☐ The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill". (21 CFR 1306.13[b], CCR 1745)

☐☐☐ The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it ~~must be~~is reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&S 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

☐☐☐ All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR1717.4).

☐☐☐ Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (1717.4[e])

~~Yes No N/A~~

☐☐☐ All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (1717.4[c])

Yes No N/A

☐☐☐ Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (1717.4[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

20. Automated Dispensing/Delivery Devices

Yes No N/A

☐☐☐ Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

☐☐☐ The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342)

☐☐☐ For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of ~~Health Services~~Public Health, the following is required:

Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])

A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])

Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

☐☐☐ If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])

Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430)

☐☐☐ A log is maintained for drugs pre-packed for future dispensing. (CCR 1716.2)

☐☐☐ Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Refill Pharmacy

Yes No N/A

☐☐☐ Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ Some or all pharmacy refill orders are processed by another California licensed pharmacy. (1707.4[a])

If the answer is "yes" , name of refilling pharmacy(s) _____

If the answer to both questions above is "no" or "not applicable" go to section 22.

~~Yes No N/A~~

☐☐☐ Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (1707.4[a][1])

☐☐☐ Refill prescription label meets requirements of B&PC 4076 and shows the name and address of the refilling and or originating pharmacy. (1707.4[a][2])

☐☐☐ Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (1707.4[a][3])

☐☐☐ Both pharmacies maintain complete and accurate records or refill. (1707.4[a][4])

☐☐☐ Both pharmacies are responsible for accuracy of the refilled prescription. (1707.4[a][5])

Yes No N/A

☐☐☐ Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Policies and Procedures

Yes No N/A

☐☐☐ There are written policies and procedures in place for:

The pharmacist's administration of immunizations by injection pursuant to a prescriber's order; (B&PC 4052[a][5][A][iii])

Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])

Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present. (B&PC 4059.5[f][1])

Compliance with Title 7 – Combat Methamphetamine Epidemic Act of 2005.

Reporting requirements to protect the public. (B&PC 4104)
Preventing the dispensing of a prescription drug that is contrary to the law. (B&PC 733)

Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition. (B&PB 733)

Yes No N/A

☐☐☐ Does your pharmacy employ the use of a common electronic file?

If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

☐☐☐ The pharmacy has a designated area or cleanroom for the preparation of sterile products from a non-sterile source that has the following:

An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom; (B&PC 4127.7[a])

A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

An ISO class 5 cleanroom (B&PC 4127.7[b]); and

A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

☐☐☐ The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility & Equipment Standards

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])

☐☐☐ Only those who are properly attired pursuant to (CCR 1751.4) are allowed in the cleanroom. (CCR 1751.01[b])

☐☐☐ All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (B&PC 1751.01[d])

~~Yes No N/A~~

☐☐☐ There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Compounding, filling, and labeling of sterile injectable compounds;

Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

Equipment and supplies;

Training of staff in preparation of sterile injectable products;
Training of patient and/or caregiver in the administration of compounded sterile injectable products;

Procedures for the handling and disposal of cytotoxic agents;

Quality assurance program; and

Record keeping requirements.

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.02 [b])

☐☐☐ If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

☐☐☐ Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

Competency evaluation;

Storage and handling of products and supplies;

Storage and delivery of final products;

Process validation;

Personnel access and movement of materials into and near the controlled area;

Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;
Sterilization; and

End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

Yes No N/A

☐☐☐ The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)
Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Name and concentrations of ingredients contained in the product;

Instructions for storage and handling; and

A special label that states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

e. Record Keeping Requirements

Yes No N/A

☐☐☐ Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])

☐☐☐ Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])

The training and competency evaluation of employees in sterile product procedures;

Refrigerator and freezer temperatures;

Certification of the sterile compounding environment;

Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

Inspection for expired or recalled pharmaceutical products or raw ingredients; and

Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

Yes No N/A

☐☐☐ The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.4[a])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is <u>not</u> used:

Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])

Individuals in the cleanroom wear a low-shedding coverall, head cover, facemask, and shoe covers; (CCR 1751.4[b][1])

No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])

Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and

Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes No N/A

☐☐☐ Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])

~~Yes No N/A~~

☐☐☐ The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])

☐☐☐ Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])

☐☐☐ The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e])

☐☐☐ The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

Aseptic technique;

Pharmaceutical calculations and terminology;

Sterile product compounding documentation;

Quality assurance procedures;

Proper gowning and gloving technique;

General conduct in the controlled area;

Cleaning, sanitizing, and maintaining equipment used in the controlled area;

Sterilization techniques; and

Container, equipment, and closure system selection.

Yes No N/A

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

☐☐☐ Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751[e][2])

☐☐☐ Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751[e][2])

☐☐☐ Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

I. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

☐☐☐ The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])
Cleaning and sanitization of the parenteral medication preparation area;

Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens;

The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

Steps to be taken in the event of a drug recall; and

Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3]).

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

Yes No N/A

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25.Compounding Non-Sterile Drug Products

a. Compounding Unapproved Drugs for Prescriber Office Use (CCR 1716.1):

Yes No N/A

☐☐☐ Pharmacy compounds unapproved drugs for prescriber office use based upon a reasonable quantity

☐☐☐ Establishing reasonable quantity is based on the intended use of the compounded medication and nature of the prescriber's practice.

☐☐☐ Compounded medications means medications actively compounded by the pharmacy supplying them to a prescriber.

☐☐☐ Prescriber office use means application or administration in the prescriber's office or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Record Keeping Requirements – Compounding for Future Furnishing (CCR1716.2)

Yes No N/A

☐☐☐ For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

The date of preparation (compounding);

The name of the manufacturer, the lot number of all components used to compound the product;

The expiration date of each component (if not available, the source and date of purchase)

A pharmacy lot number or identification number;

☐☐☐ A master formula for each compounded drug product in a readily retrievable form to also include:

The amount of each component, compounding directions, etc;

A beyond-use-date not to exceed 180 days or the shortest expiration date of any component (unless the pharmacy possesses stability data for each product compounded by the pharmacy beyond the 180 days);

The signature/initials of the person(s) who compounded the drug product; and

The signature/initials of the pharmacist who checked the final product.

☐☐☐ The final quantity of drug product compounded (number of individual units by weight or volume and package size);

Yes No N/A

☐☐☐ Status/disposition of any quarantined compounded drug products to also include release date; and

☐☐☐ Status/disposition of any compounded drug products that failed to meet standards for quality purity or strength.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

26. NUCLEAR PHARMACY

Yes No N/A

☐☐☐ All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ The pharmacy possesses a current Sterile Compounding Permit (B&P 4127) and is compliant with CCR 1751. (must also complete section 21)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
(800) 498-0911 Ext. 5
~~www.lawtech-pub.com~~www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street~~, Bldg. III, Unit 3~~
Manchester, NH 03103
Phone: (888) ~~539-3370~~492-7341
Fax: 877-508-6704

~~**Bureau of Narcotic Enforcement**~~
~~Security Prescription~~
~~1102 Q Street, 6th Fl.~~
~~Sacramento, CA 95817~~
~~(916) 319-9062~~
~~Fax: (916) 319-9448~~
~~http://www.ag.ca.gov/bne~~
CURES
4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

PRESCRIBER BOARDS:

Medical Board of California
~~1426 Howe Avenue, Suite 542~~2005 Evergreen St., Suite 1200
Sacramento, CA ~~9582~~95815
(800) 633-2322
(916) 263-~~2499~~2382
Fax: (916) 263-~~2387~~2944
http://www.mbc.ca.gov

Dental Board of California
~~1432 Howe Ave. #85~~ 2005 Evergreen St., Suite 1550
Sacramento, CA ~~9582~~95815
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-~~8637~~7697
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
~~2720 Gateway Oaks Drive, #350~~1300 National Drive, Suite 150
Sacramento, CA ~~9583~~95834
(916) ~~263-3100~~928-8390
fax: (916) ~~263-3117~~928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
~~1424 Howe Avenue, #35~~2500 Evergreen St., Suite 1100
Sacramento, CA ~~9582~~95815
(916) 561-8780
fax: (916) 263-2671
http://www.~~physicianassistant~~pac.ca.gov

Board of Podiatric Medicine
~~1420 Howe Avenue, #8~~2005 Evergreen St., Suite 1300
Sacramento, CA ~~9582~~95815
~~(800) 633-2322~~
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
~~1420 Howe Avenue, #6~~2005 Evergreen St., Suite 2250
Sacramento, CA ~~9582~~95815
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

FEDERAL AGENCIES:

Food and Drug Administration
– Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website: http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
DEA Registration Support (all of CA):
(800) 882-9539
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Online DEA 222 Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-~~5402~~5406

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
(888) 415-9822 or (213) 621-6960 (Registration)
(213) 621-6942 ~~or 6952~~
(Diversion or Investigation)

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: ~~(909) 328-6000 or~~
~~(909) 328-6200~~(951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: ~~(916) 480-7100 or~~
(916) 480-7250

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Theft Reports or Diversion: (415) 436-~~7854~~-7900

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Diversion or Investigation: ~~(408) 291-7620 or~~
(408) 291-2631

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENNEGGER, GOVERNOR

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed also.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):

1. _____ RPH # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (continued): (Please use an additional sheet if necessary)

4. _____ RPH # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
6. _____ RPH # _____ Exp. Date: _____
7. _____ RPH # _____ Exp. Date: _____
8. _____ RPH # _____ Exp. Date: _____
9. _____ INT # _____ Exp. Date: _____
10. _____ INT # _____ Exp. Date: _____
11. _____ INT # _____ Exp. Date: _____
12. _____ TCH # _____ Exp. Date: _____
13. _____ TCH # _____ Exp. Date: _____
14. _____ TCH # _____ Exp. Date: _____
15. _____ TCH # _____ Exp. Date: _____
16. _____ TCH # _____ Exp. Date: _____
17. _____ TCH # _____ Exp. Date: _____
18. _____ TCH # _____ Exp. Date: _____

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

☐☐☐ The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4117, CCR 1714)

☐☐☐ The pharmacy has procedures in place for taking action to protect the public when a licensed individual employer by or with the pharmacy is impaired to the extent that it affects his or her ability to practice safely. (B&PC 4104[a])

☐☐☐ The pharmacy reports to the board information on any licensed individual any admission by the individual affecting his or her ability to practice safely, and admission of theft, diversion or self-use, evidence documenting the behavior as well as any terminations that result from the behavior. (B&PC 4104)

☐☐☐ The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐☐☐ The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)

☐☐☐ The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ The pharmacy has a readily accessible restroom. (CCR 1714)

☐☐☐ The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

☐☐☐ Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[dc])

☐☐☐ Does the pharmacy compound sterile injectable drugs?
(If yes, complete section 24 – "Compounding Sterile Injectable Drugs")

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Nursing Stations

Yes No N/A

☐☐☐ Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ The pharmacist completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (22 CCR 70263[q][10])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Delivery of Drugs

Yes No N/A

☐☐☐ Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

☐☐☐ Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

☐☐☐ A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);

Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);

The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);

The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and

The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Drug Stock

Yes No N/A

☐☐☐ The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 1714 (b), 70263[q])

☐☐☐ All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.2[b])

☐☐☐ Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

☐☐☐ Is the PIC serving concurrently as the ~~exemptee~~ designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1 ~~f~~[d])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4052, 4052.2, CCR 1793.1)

☐☐☐ Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2. (B&PC 4027, 4051, 4052, 4052.2)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than two interns at any one time. (B&PC 4023.5, 4030, 4114, CCR 1726)

☐☐☐ All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2)

☐☐☐ The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])

Yes No N/A

☐☐☐ Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

☐☐☐ A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

☐☐☐ The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

☐☐☐ The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

Pharmacists are deployed to the inpatient care setting to provide clinical services.

Compounded or repackaged products are previously checked by a pharmacist.

The overall operations are the responsibility of the pharmacist-in-charge.

The pharmacy technician check technician program is under the direct supervision of the pharmacist as specified in the policies and procedures.

There is an ongoing evaluation of the program that uses specially trained pharmacy technicians to check the work of other pharmacy technicians.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

9. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACY PRACTICE

10. Pharmaceutical Service Requirements

Yes No N/A

☐☐☐ The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

Basic information concerning investigational drugs and adverse drug reactions;

Repackaging and compounding records;

Physician orders;

Wards, nursing stations and night stock medications;

Drugs brought into the facility by patients for storage or use;

Bedside medications;

Emergency drug supply;

Pass medications;

Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;

Routine distribution of inpatient medications;

Preparation, labeling and distribution of IV admixtures and cytotoxic agents;

Handling of medication when pharmacist not on duty; and

Use of electronic image and data order transmissions.

☐☐☐ The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

Destruction of controlled substances; and

Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

11. Medication/Chart Order

Yes No N/A

☐☐☐ The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

☐☐☐ The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])

☐☐☐ A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

12. Labeling and Distribution

Yes No N/A

☐☐☐ Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration.(B&PC 4076, CCR 1751.2)

☐☐☐ The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Duration of Drug Therapy

Yes No N/A

☐☐☐ The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ The record for quality assurance review for a medication error contains: (CCR 1711[e])

Date, location, and participants in the quality assurance review;

Pertinent data and other information related to the medication error(s) reviewed;

Findings and determinations;

Recommended changes to pharmacy policy, procedure, systems or processes, if any.

Yes No N/A

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

16. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

Prescription records (CCR 4081[a])

Purchase invoices for all prescription drugs (4081[b])

Biennial controlled substances inventory (21 CFR 1304.11)

U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)

Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

Record documenting return of drugs to wholesaler or manufacturer (CCR 4081)

Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)

☐☐☐ Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 22, 1988] 503, B&PC 4160)

☐☐☐ If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)

Yes No N/A

☐☐☐ A controlled substances inventory is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11)

☐☐☐ Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ DEA Forms-222 are properly executed. (21 CFR 1305.09)

☐☐☐ When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form-222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1309.09)

☐☐☐ Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

☐☐☐ Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. After-Hours Supply of Medication

Yes No N/A

☐☐☐ The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

☐☐☐ The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (Title 22 CCR 70263[f][2])

☐☐☐ The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

20. Emergency Room Dispensing

Yes No N/A

☐☐☐ A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply (B&PC 4068[a]):

The hospital pharmacy is closed and there is no pharmacist available in the hospital;

The dangerous drug is acquired by the hospital pharmacy;

The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;

The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and

The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

Yes No N/A

☐☐☐ The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

☐☐☐ The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

☐☐☐ The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label an prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

☐☐☐ Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15. CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Central Fill

Yes No N/A

☐☐☐ Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

- If the answer is yes, name of hospital: _____

☐☐☐ Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

- If the answer is "yes", name of supplying pharmacy: _____
- If the answer to this and the previous question is "no" or "not applicable" go to Section 23.

☐☐☐ Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

☐☐☐ Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3]

☐☐☐ Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Policies and Procedures

Yes No N/A

☐☐☐ There are written policies and procedures in place for:

The assurance that each patient received information regarding each medication given at the time of discharge.

Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (B&PC 4104[b])

Reporting to the board within 30 days of the receipt or development of information as specified in B&PC 4104[c][1-6])

Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility (B&PC 4074, CCR 1707.2[b][3]); and

Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions (if applicable)

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC Permit # _____ or

Name of accreditation agency _____

☐☐☐ The pharmacy has a designated area or cleanroom for the preparation of sterile products from one or more non-sterile ingredient that has the following:

An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom (B&PC 4127.7[a]);

A positive air pressure differential in the cleanroom that is relative to adjacent areas (B&PC 4127.7[a]);

An ISO class 5 cleanroom ((B&PC 4127.7[b]);

A barrier isolator that provides an ISO class 5 environment for compounding ((B&PC 4127.7[c]); and

The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility and Equipment Standards

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])

☐☐☐ Only those who are properly attired (pursuant to ((CCR 1751.4) are allowed in the cleanroom. ((CCR 1751.01[b])

☐☐☐ All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination. (B&PC 1751.01[d])

☐☐☐ There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Compounding, filling, and labeling of sterile injectable compounds;

Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

Equipment and supplies;

Training of staff in preparation of sterile injectable products;

Training of patient and/or caregiver in the administration of compounded sterile injectable products;

Procedures for the handling and disposal of cytotoxic agents;

Quality assurance program; and

Record keeping requirements.

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. ((CCR 1751.02 [b])
If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

☐☐☐ Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

Competency evaluation;

Storage and handling of products and supplies;

Storage and delivery of final products;

Process validation;

Personnel access and movement of materials into and near the controlled area;

Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations; A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of

disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

Sterilization; and

End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

Yes No N/A

☐☐☐ The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)
Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Name and concentrations of ingredients contained in the product;

Instructions for storage and handling; and
A special label which states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

e. Record keeping Requirements

Yes No N/A

☐☐☐ Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])

Yes No N/A

☐☐☐ Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])

The training and competency evaluation of employees in sterile product procedures;

Refrigerator and freezer temperatures;
Certification of the sterile compounding environment;

Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

Inspection for expired or recalled pharmaceutical products or raw ingredients; and
Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

Yes No N/A

☐☐☐ The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn. (CCR 1751.4[a])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used:

Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])

Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.4[b][1])

No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])

Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and

Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes No N/A

☐☐☐ Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])

☐☐☐ The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])

☐☐☐ Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])

☐☐☐ The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e])

☐☐☐ The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform

their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

Aseptic technique;

Pharmaceutical calculations and terminology;

Sterile product compounding documentation;

Quality assurance procedures;

Proper gowning and gloving technique;

General conduct in the controlled area;

Cleaning, sanitizing, and maintaining equipment used in the controlled area;

Sterilization techniques; and

Container, equipment, and closure system selection.

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.

Each person's proficiency and continuing training is reassessed every 12 months.

Results of these assessments are documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

i. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end product meets the required specifications by periodic sampling. (CCR 1751.7[a])

☐☐☐ The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])

Cleaning and sanitization of the parenteral medication preparation area;

Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens; The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

Steps to be taken in the event of a drug recall; and

Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3])

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

Yes No N/A

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
~~www.lawtech-pub.com~~
www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, ~~Bldg. III, Unit 3~~
Manchester, NH 03103
Phone: (888) ~~539-3370~~492-7341
Fax: 877-508-6704

~~**Bureau of Narcotic Enforcement**~~
~~Security Prescription and CURES Programs~~
~~1102 Q Street, 6th Fl.~~
~~Sacramento, CA 95817~~
~~(916) 319-9062~~
~~Fax: (916) 319-9448~~
~~http://www.ag.ca.gov/bne~~
CURES
4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

PRESCRIBER BOARDS:

Medical Board of California
~~1426 Howe Avenue, Suite 54~~2005 Evergreen St., Suite 1200
Sacramento, CA ~~9582~~595815
(800) 633-2322
(916) 263-~~24992~~382
Fax: (916) 263-~~23872~~944
http://www.mbc.ca.gov

Dental Board of California
~~1432 Howe Ave. #852~~005 Evergreen St., Suite 1550
Sacramento, CA ~~9582~~595815
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-~~8637~~7697
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
~~2720 Gateway Oaks Drive, #350~~1300 National Drive, Suite #150
Sacramento, CA ~~9583~~95834
(916) ~~263-3100~~928-8390
fax: (916) ~~263-3117~~928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
~~1424 Howe Avenue, #352~~005 Evergreen St., Suite 1100
Sacramento, CA ~~9582~~595819
(916) 561-8780
fax: (916) 263-2671
~~http://www.physicianassistant.ca.gov~~www.pac.ca.gov

Board of Podiatric Medicine
~~1420 Howe Avenue, #82~~005 Evergreen St., Suite 1300
Sacramento, CA ~~9582~~595815
~~(800) 633-2322~~
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
~~1420 Howe Avenue, #82~~005 Evergreen St., Suite 2250
Sacramento, CA ~~9582~~595815
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

FEDERAL AGENCIES:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website: http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
DEA Registration Support (all of CA):
(800) 882-9539
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Online DEA 222 Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-~~5402~~5406

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
(888) 415-9822 or (213) 621-6960 (Registration)
(213) 621-6942 ~~or 6952~~
(Diversion or Investigation)

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: ~~(909) 328-6000 or~~
~~(909) 328-6200~~(951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: ~~(916) 480-7100 or~~
(916) 480-7250

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Theft Reports or Diversion: (415) 436-~~7854~~7900

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Diversion or Investigation: ~~(408) 291-7620 or~~
(408) 291-2631

Board of Pharmacy
Specific Language to amend Section 1715

Amend Section 1784 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new wholesaler permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a wholesaler to a new address.
(c) The components of this assessment shall be on Form 17M-26 (rev. ~~812/14/2006~~ 10/2008) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

WHOLESALER
DANGEROUS DRUGS & DANGEROUS DEVICES
SELF- ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B & P) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC
○ non- licensed owner ○ Other (please specify) _____

CA Wholesaler Permit #_____ Expiration Date_____

Other Permit #_____ Expiration Date_____

DEA Registration #_____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Daily_____Sat_____Sun_____24 Hours ○

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License #_____ Expiration Date_____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

1. _____ DR#/RPH#_____Exp. Date _____
2. _____ DR#/RPH#_____Exp. Date _____
3. _____ DR#/RPH#_____Exp. Date _____
4. _____ DR#/RPH#_____Exp. Date _____
5. _____ DR#/RPH#_____Exp. Date _____
6. _____ DR#/RPH#_____Exp. Date _____
7. _____ DR#/RPH#_____Exp. Date _____
8. _____ DR#/RPH#_____Exp. Date _____
9. _____ DR#/RPH#_____Exp. Date _____
10. _____ DR#/RPH#_____Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B & P 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note:: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B & P 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ Are clean and orderly
☐ ☐ ☐ Are well ventilated
☐ ☐ ☐ Are free from rodents and insects
☐ ☐ ☐ Are adequately lit
☐ ☐ ☐ Have plumbing in good repair
☐ ☐ ☐ Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐ Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐ Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

Yes No N/A

☐ ☐ ☐ Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

The wholesale premises is equipped with the following specific security features:

☐ ☐ ☐ There is an alarm to detect after-hours entry. (CCR 1780[c][1]).
☐ ☐ ☐ The outside perimeter of the building is well lit (CCR 1780[c][3]).
☐ ☐ ☐ The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

Yes No N/A

☐ ☐ ☐ Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B & P 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B & P 4081[b])

☐ ☐ ☐ Is the designated representative-in-charge responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B & P 4160[d])

☐ ☐ ☐ The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B & P 4305.5[a])

☐ ☐ ☐ The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B & P 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

☐ ☐ ☐ The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B & P 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Designated Representative/Pharmacist

Yes No N/A

☐ ☐ ☐ If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B & P 4100, 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B & P 4163[b], 4169)

Yes No N/A

☐ ☐ ☐ If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B & P 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ Is all drug stock open for inspection during regular business hours? (B & P 4081[a])

☐ ☐ ☐ Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B & P 4167)

☐ ☐ ☐ Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B & P 4342[a])

Yes No N/A

☐ ☐ ☐ Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

☐ ☐ ☐ When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

Describe how you verify a business or person is appropriately licensed. (B & P 4059.5[a] [b][d], B & P 4169)

_____

_____

List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ Are drugs only furnished by your business to an authorized person? (B & P 4163[a]) Note: An authorized person can be a business or natural person.

Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ your business is a "reverse distributor"?

☐ ☐ ☐ the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B & P 4126.5[a])

Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ transacted with a business licensed with this board as a wholesaler or pharmacy?

☐ ☐ ☐ free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ confirmed to not be beyond their use date (expired drugs)? (B & P 4169)

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ comply with all applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B & P 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Effective January 1, 2009, an electronic pedigree must accompany all drugs (B & P 4163), even those for which your business is an authorized distributor.

☐ ☐ ☐ If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B & P 4380)

☐ ☐ ☐ Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B & P 4341, B & P 651, CCR 1766)

☐ ☐ ☐ Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B & P 650)

_____

_____

Yes No N/A

☐ ☐ ☐ Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B & P 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

Yes No N/A

☐ ☐ ☐ Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B & P 4166[a])

List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B & P 4059.5[a])

☐ ☐ ☐ Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B & P 4059[d])

☐ ☐ ☐ All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B & P 4059.5[c])

☐ ☐ ☐ If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B & P 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

11. Controlled Substances

Yes No N/A

☐ ☐ ☐ Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

Yes No N/A

☐ ☐ ☐ Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

☐ ☐ ☐ Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, has created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])

☐ ☐ ☐ If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

☐ ☐ ☐ If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

Yes No N/A

☐ ☐ ☐ If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances.(CFR 1301.74[f])

☐ ☐ ☐ If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☐ When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1309.13[b])

☐ ☐ ☐ For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[c])

☐ ☐ ☐ Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances?

☐ ☐ ☐ Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the

making? (B & P 4081, CCR 1718, CFR 1305.09[d], 1305.17[a] [b], and H & S 11252, 11253, 1304.03)

Yes No N/A

☐ ☐ ☐ Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])

☐ ☐ ☐ Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)

☐ ☐ ☐ Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

12. Policies and Procedures

Does this business maintain and adhere to policies and procedures for:

Yes No N/A

☐ ☐ ☐ Receipt of drugs?
☐ ☐ ☐ Security of drugs?
☐ ☐ ☐ Storage of drugs? (including maintaining records to document proper storage)
☐ ☐ ☐ Inventory of drugs? (including correcting inaccuracies in inventories)
☐ ☐ ☐ Distributing drugs?
☐ ☐ ☐ Identifying, recording and reporting theft or losses?
☐ ☐ ☐ Correcting errors?
Physically quarantining and separating:
☐ ☐ ☐ returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?
☐ ☐ ☐ drugs that have been partially used?
☐ ☐ ☐ drugs where the outer or secondary seals on the container have been broken?
☐ ☐ ☐ drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

Yes No N/A

☐ ☐ ☐ drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

13. Training

Yes No N/A

☐ ☐ ☐ Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B & P 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B & P 4059[d])

☐ ☐ ☐ Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])

☐ ☐ ☐ Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs,

the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B & P 4059[b])

☐ ☐ ☐ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B & P 4081[a], 4105[c], 4081, 4332, 4059.5[a]) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.

☐ ☐ ☐ Are all purchase and sales records retained in a readily retrievable form? (B & P 4105[a])

☐ ☐ ☐ Is a current accurate inventory maintained for all dangerous drugs? (B & P 4081, 4332, 1718)

☐ ☐ ☐ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B & P 4105[b])

☐ ☐ ☐ Are required records stored off-site only if a board issued written waiver has been granted?

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

Yes No N/A

☐ ☐ ☐ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

Yes No N/A

☐ ☐ ☐ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

☐ ☐ ☐ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B & P 4162[a][4]):

_____

_____

Yes No N/A

☐ ☐ ☐ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B & P 4083)

☐ ☐ ☐ Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B & P 4315[e])

☐ ☐ ☐ If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B & P 4101[b], 4305.5[c].

☐ ☐ ☐ The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B & P 4305.5[a])

Yes	No	N/A	
☐	☐	☐	The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
☐	☐	☐	The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])
☐	☐	☐	Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
☐	☐	☐	The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B & P 4201[i], CCR 1709[b])
☐	☐	☐	When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B & P 4164[a])
☐	☐	☐	Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must: 1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities 2. identify purchases of any dangerous drugs at preferential or contract prices 3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B & P 4164[b])
☐	☐	☐	I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B & P 4201[g])
☐	☐	☐	The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
☐	☐	☐	If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

17. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B & P 4107, CFR 1305.11[a], B & P 4059.5[e])

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____
hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

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Legal References

All references to California Business & Professions Code (B & P) are Chapter 9, Division 2 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Code of Regulations (CCR) are to Title 16 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Health & Safety Code (H & S) are to Division 10, Uniform Controlled Substances Act (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) or Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws http://www.dhs.ca.gov/fdb/PDF/Sherman%202006.PDF

All references to United States Code of Federal Regulations (CFR) are Title 21, Chapter II Part 1300, Drug Enforcement Administration, Food and Drugs and codified Controlled Substances Act (CSA) (http://www.deadiversion.usdoj.gov/21cfr/index.html).

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
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(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
(800) 498-0911 Ext. 5
~~www.lawtech.pub.com~~
www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
~~1426 Howe Avenue, Suite 54~~
2005 Evergreen St., Suite 1200
Sacramento CA ~~95825~~ 95815
(800) 633-2322
(916) 263-~~24992382~~
fax: (916) 263-~~23872944~~
http://www.mbc.ca.gov

Dental Board of California
~~1432 Howe Ave. #85~~ 2005 Evergreen St., Suite 1550
Sacramento, CA ~~95825~~ 95815
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-~~3350~~ 7697
fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
~~2720 Gateway Oaks Drive, #350~~ 1300 National Drive, Suite 150
Sacramento, CA ~~95833~~ 95834
(916) ~~263-3100~~ 928-8390
fax: (916) ~~263-3117~~ 928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
~~1424 Howe Avenue, #35~~ 2005 Evergreen St., Suite 1100
Sacramento, CA ~~95825~~ 95815
(916) 561-8780
fax: (916) 263-2671
~~http://www.physicianassistant.ca.gov~~
www.pac.ca.gov

Board of Podiatric Medicine
~~1420 Howe Avenue, #8~~
2005 Evergreen St., Suite 1300
Sacramento, CA ~~95825~~ 95815
~~(800) 633-2322~~
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
~~1420 Howe Avenue, #6~~
2005 Evergreen St., Suite 2250
Sacramento, CA ~~95825~~ 95815
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

Federal Agencies:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA Registration Support (all of CA):
(800) 882-9539

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
(888) 415-9822 or (213) 621-6960
(Registration)
(213) 621-6942 ~~or 6952~~
(Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Theft Reports or Diversion: (415) 436-~~7854~~ 7900

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: ~~(916) 480-7100~~ ~~or~~ (916) 480-7250

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: ~~(909) 328-6000 or (909) 328-6200~~ (951) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402~~6~~

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Diversion or Investigation: (510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251 ~~or~~
~~(415) 436-7900~~
Diversion or Investigation: ~~(408) 291-7620~~ ~~or~~ (408) 291-2631

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new veterinary food-animal drug retailer permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.
(c) The components of this assessment shall be on Form 17M-40 entitled "Veterinary Food-Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.
(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

VETERINARY FOOD-ANIMAL DRUG RETAILER SELF ASSESSMENT

All legal references used throughout this self-assessment form are explained on Page 17
All references to "drugs" throughout this self–assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&P) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) Dangerous drug or dangerous device means any drug or device unsafe for self-use in humans or animals.

Definitions:

"Veterinary Food-Animal Drug Retailer" (vet retailer) is an area, place or premises, other than a pharmacy that holds a valid license from the California State Board of Pharmacy as a wholesaler and, in and from which veterinary drugs for food-producing animals are dispensed pursuant to a prescription from a licensed Veterinarian. It is a separate and additional license from a wholesaler license. Veterinary food–animal drug retailer includes but is not limited to any area, place or premises described in a permit issued by the board wherein veterinary food-animal drugs (as defined in Business & Professions Code section 4042) are stored, possessed, or repackaged, and from which veterinary drugs are furnished, sold, or dispensed at retail pursuant to a prescription from a licensed veterinarian.

'Veterinary Food–Animal Drugs" include any drug to be used in food-producing animals bearing the legend "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian" or words of similar import. Also included is any drug as defined in Section 14206 of the Food and Agriculture Code that is used in a manner that would require a veterinary prescription.

Veterinary Food-Animal Drug Retailer Name_____

Address_____

Phone_____

E-mail address (optional)_____

Ownership: Please mark one

☐ Sole owner ☐ Partnership ☐ Corporation ☐ LLC

☐ Non-licensed owner ☐ other (please specify) _____

CA Veterinary Food-Animal Drug Retailer Permit #_____ Expiration Date_____

CA Wholesaler Permit #_____ Expiration Date_____

DEA Registration #_____ Expiration Date_____

Date of most recent DEA Inventory_____

Hours: Daily _____Sat_____ Sun_____ 24 hours_____

Designated representative-in charge (DRIC) /pharmacist (RPH)_____

DRIC License # / RPH License #_____ Expiration Date_____

Licensed Veterinary Food-Animal Drug Retailer Staff (designated representative (DRep, pharmacist):

1._____DRep/RPH#_____ Exp. Date_____

2._____ DRep/RPH#_____Exp. Date_____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐☐☐ Review the current veterinary food-animal drug retailer permit for this business. Are the listed owners correct and is the listed address correct? If either is incorrect, notify the board in writing. (B&PC 4196 [a] [d])
Attach a copy of the notification letter to the board to this document.

CORRECTIVE ACTION OR ACTION PLAN_____

_____

2. Facility

Yes No N/A

☐☐☐ Are only pharmacists, intern pharmacists, designated representatives, and authorized officers of the law, or a person authorized to prescribe, permitted in the area place or premises described in the permit as a veterinary food-animal drug retailer without supervision? (B&P 4196[c])

☐☐☐ Is a pharmacist or designated representative responsible for any person who enters the premises for clerical, inventory control, housekeeping, delivery, maintenance, or similar functions related to the business of a veterinary food animal drug retailer? (B&P 4196[c])

☐☐☐ Are all veterinary food-animal drugs stored in a secure, lockable area? (B&P 4197[a][1])

Premises, Fixtures and equipment: (B&P 4197[a][2])

☐☐☐ Fixtures and equipment -Clean and orderly
☐☐☐ Premises - dry
☐☐☐ Premises - well ventilated
☐☐☐ Premises - Adequately lighting

CORRECTIVE ACTION OR ACTION PLAN_____

_____

DRIC Initials _____

3. Designated Representative-in-Charge/Owner Responsibilities

Yes No N/A

☐☐☐ Are the owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory? (B&P 4081[b])

☐☐☐ Is the designated representative-in-charge responsible for the veterinary food-animal drug retailer's compliance with all state and federal laws related to practice as a veterinary food-animal drug retailer? (B&P 4196[d]).

☐☐☐ Has the owner notified the board within 30 days of the termination of the designated representative-in-charge or pharmacist? (B&P 4305.5[a])

☐☐☐ Has the owner identified and notified the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge? (B & P 4196[d], 4331[b]. The appropriate form for this notification is a "Change of Designated Representative-in-Charge", which is available on the board's web site.

☐☐☐ Has any designated representative-in-charge who ends his or her employment at a wholesaler, notified the board within 30 days? (B & P 4305.5[c], 4101[b]. This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN_____

_____

4. Designated Representative/Pharmacist

Yes No N/A

☐☐☐ Does your veterinary food-animal drug retailer operate only when a pharmacist or veterinary designated representative is on the premises? (4053[c])

☐☐☐ Is the address of the veterinary designated representative(s) current on their printed permit? (B&P4100,1704)

☐☐☐ If a veterinary designated representative or pharmacist changes his/her name or personal address of record, he/she will notify the board in writing within 30 days? (B&P 4100, CCR 1704)

☐☐☐ A pharmacist or veterinary retailer designated representative only dispenses drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian? (CCR 1780.1[d])

☐☐☐ Only a pharmacist or the veterinary designated representative receives an oral order for a veterinary food-animal drug from the veterinarian? (CCR 1780.1[d])

DRIC Initials _____

Yes No N/A

☐☐☐ A written copy of any oral prescription is sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐☐☐ Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&P 4163[b], 4169)

CORRECTIVE ACTION OR ACTION PLAN_____

_____

6. Receipt of Drugs by this Business

Yes No N/A

☐☐☐ When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B&P 4059.5[a])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

7. Drug Stock

Yes No N/A

☐☐☐ Is all drug stock open for inspection during regular business hours? (B&P 4081[a])

☐☐☐ Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&P 4342[a])

☐☐☐ If dangerous drugs, legend drugs or extra label use drugs are returned to the veterinary food-animal drug retailer from a client are they treated as damaged or outdated prescription drugs and stored in the quarantine area specified in California Code of Regulations section 1780(3)(1) and are not returned to stock, or dispensed, distributed or resold? (CCR 1780.1)

DRIC Initials _____

CORRECTIVE ACTION OR ACTION PLAN_____

_____

8. Prescription Dispensing

Yes No N/A

☐☐☐ Are dangerous drugs and extra label use drugs for use on food producing animals dispensed to clients pursuant to a prescription written by a veterinarian? (CCR 1780.1[a][d])

☐☐☐ Are dangerous drugs, and extra label use drugs prepared and labeled by a pharmacist or designated representative only? (CCR 1781.1[d])

☐☐☐ A veterinarian's prescription for a food-producing animal can only be refilled if the initial prescription issued indicated a specific number of refills. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead a new prescription must be obtained from the veterinarian? (CCR 1780.1[g][1])

☐☐☐ No veterinary food-animal drug prescriptions are refilled over six months from the date of issuance of the initial order? (CCR 1780.1[g][2])

☐☐☐ Are prescriptions partially filled? If unable to fill the full quantity of drugs prescribed, fill and ship a portion of the order, so long as the full quantity is shipped within 30 days? (CCR 1780.1[j])

When partially filling a prescription, does the pharmacist or veterinary designated representative note the following information on the written prescription for each date the drugs are shipped: (CCR 1780.1[j])

☐☐☐ Quantity shipped?
☐☐☐ Date shipped?
☐☐☐ Number of containers shipped?
☐☐☐ If multiple containers, each container must be sequentially numbered?

☐☐☐ If unable to fill the full quantity of a prescription within 30 days, has a new veterinarian's prescription been written to fill the remainder of the drugs originally prescribed? (CCR 1780.1[j])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

DRIC Initials _____

9. Prescription Labeling

Yes No N/A

☐☐☐ Does only a pharmacist or veterinary designated representative prepare and affix the label to a veterinary food-animal drug product?

Pursuant to a veterinarian's prescription, are prescription labels affixed to all drug containers that include: (CCR 1780.1[h][1-14])

☐☐☐ Active ingredients or the generic name(s) of the drug?
☐☐☐ Manufacturer of the drug?
☐☐☐ Strength of the drug dispensed?
☐☐☐ Quantity of the drug dispensed?
☐☐☐ Name of the client?
☐☐☐ Species of food-producing animal for which the drug is described?
☐☐☐ Condition for which the drug is prescribed?
☐☐☐ Directions for use?
☐☐☐ Withdrawal time?
☐☐☐ Cautionary statements, if any?
☐☐☐ Name of the veterinarian prescriber?
☐☐☐ Date dispensed?
☐☐☐ Name and address of the veterinary food-animal drug retailer?
☐☐☐ Prescription number or another means of identifying the prescription?
☐☐☐ If an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription? (container 1 of 6, container 2 of 6)
☐☐☐ Manufacture's expiration date?

CORRECTIVE ACTION OR ACTION PLAN_____

_____

10. Repackaging

Definition - Repackaging within the meaning of B&P 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a) or extra label use drugs, so long as the seals on the individual containers are not broken.

Yes No N/A

☐☐☐ Are only sealed original manufacturer's containers labeled for distribution to clients? Veterinary retailers or wholesalers cannot open a container and count out or measure out any quantity of a dangerous legend or extra label use drug. (CCR 1780.1[b])

DRIC Initials _____

CORRECTIVE ACTION OR ACTION PLAN_____

_____

11. Sale or Transfer of Drugs by this Business

Yes No N/A

☐☐☐ Are all dangerous drugs and extra label drugs that are sold, only sold pursuant to a prescription issued by a veterinarian to a veterinarian's client for use on food-producing animals? (CCR 1780.1[a])

☐☐☐ No dangerous drugs or extra label drugs are sold, traded or transferred at wholesale by the veterinary retailers? (B&P 4041)

☐☐☐ Are practices in place to prevent dangerous drugs from being sold, traded or transferred if the vet retailer or wholesaler knew or reasonably should have known the drugs were adulterated as defined by CA Health & Safety Code section 111250, misbranded as defined by CA Health & Safety Code section 111335, or beyond the use date on the label? (B&P 4169[a])

☐☐☐ List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

☐☐☐ Do your advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&P 4341, 4651, CCR 1766)

☐☐☐ Do you offer any rebates, refunds, commissions or preferences, discounts, or other considerations for referring clients? If your business has any of these arrangements, please list with whom? (B&P 650)

_____

_____

If your business sells, transfers or delivers dangerous drugs outside of California, either to another state within the United States or a foreign country, do you comply with:

☐☐☐ All CA pharmacy and veterinary laws related to the distribution of drugs?
☐☐☐ The pharmacy law and veterinary laws of the receiving state within the United States?
☐☐☐ The statutes and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration?
☐☐☐ All laws of the receiving foreign country related to drugs for food producing animals?

DRIC Initials _____

Yes No N/A

☐☐☐ All applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a client in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&P 4059.5[e])

CORRECTIVE ACTION OR ACTION PLAN

12. Delivery of Drugs

Yes No N/A

☐☐☐ Upon delivery of appropriately labeled prescription drugs or extra label drugs to a client, pursuant to a veterinarian's prescription, do you obtain the signature of the client, or the client's agent, on the invoice with notations of any discrepancies, corrections or damage? (CCR 1780.1[k])

CORRECTIVE ACTION OR ACTION PLAN

13. Controlled Substances

Yes No N/A

☐☐☐ If a controlled substance is dispensed, are the labels on the containers countersigned by the prescribing veterinarian before being provided to the client? (CCR1780.1[e])

Note: Please refer to "Controlled Substances" section of the Wholesaler Self Assessment for additional controlled substance statutes, regulations, and requirements your business must follow

CORRECTIVE ACTION OR ACTION PLAN

14. Consultant Pharmacist

Yes No N/A

☐☐☐ Does your consulting pharmacist assure compliance with all statutes and regulations governing veterinary food-animal drug retailers? (B&P 4198[e])

DRIC Initials _____

Yes No N/A

☐☐☐ Does your consultant pharmacist visit routinely, but at least quarterly? (B&P 4198[e])

Does your consultant pharmacist: (B&P 4198[e])

☐☐☐ Review and revise policies and procedures?

☐☐☐ Assure compliance with state and federal statutes and regulations for labeling, storage and dispensing of veterinary food-animal drugs?

☐☐☐ Provide a written report twice yearly certifying whether or not the veterinary food-animal drug retailer is operating in compliance with the requirements of this chapter?

☐☐☐ Are these written reports readily available for inspection upon request?

CORRECTIVE ACTION OR ACTION PLAN

15. Designated Representative Training.

Yes No N/A

☐☐☐ Does your business prepare and maintain records of training and demonstrated competence for each individual employed or retained by you? (B&P 4198[b])

☐☐☐ Are records of training and demonstrated competence for each employee maintained for 3 years after the last date of employment? (B&P 4198[b])

CORRECTIVE ACTION OR ACTION PLAN

16. Quality Assurance Program

Does your business have an ongoing, documented quality assurance program, which includes but is not limited to: (B&P 4198 [c])

Yes No N/A

☐☐☐ Monitoring personnel performance?

☐☐☐ Storage of veterinary food-animal drugs?

☐☐☐ Maintenance of equipment?

☐☐☐ Dispensing of veterinary food-animal drugs?

CORRECTIVE ACTION OR ACTION PLAN

DRIC Initials _____

17. Policies and Procedures

Does your business maintain and adhere to policies and procedures for: (B&P 4198)

Yes No N/A

- ☐☐☐ Handling of veterinary food animal drugs?
- ☐☐☐ Dispensing of veterinary food animal drug?
- ☐☐☐ Staff training records?
- ☐☐☐ Cleaning of equipment?
- ☐☐☐ Storage and maintenance of veterinary food –animal drugs?
- ☐☐☐ Storage and maintenance of equipment?
- ☐☐☐ Record keeping requirements?
- ☐☐☐ Storage requirements?
- ☐☐☐ Security requirements?
- ☐☐☐ Quality assurance?

CORRECTIVE ACTION OR ACTION PLAN_____

_____

18. Record Keeping Requirements

Purchase and Sales Records

Yes No N/A

☐☐☐ Are all records of acquisition and disposition of dangerous drugs, retained on the premises, open for inspection, during regular business hours? (B&P 4081, 4332, CCR 1718)

☐☐☐ Are all prescription documents and other disposition records for dangerous drugs or extra label use drugs dispensed by a vet food-animal drug retailer kept on file and maintained on the premises for 3 years? (B&P 4198[b])

☐☐☐ Are all records of prescription refills retained by your business on the premises for 3 years? (CCR1780.1[I], B&P 4081[a], 4332)

☐☐☐ Are all purchase and sales records retained in a readily retrievable form? (B&P 4105[a])

Yes No N/A

☐☐☐ Are records of shipment of labeled dangerous drugs to clients (also known as an expanded invoice) included in the client's shipment? This document includes: (CCR1780.1[i])

- ☐☐☐ Drug name?
- ☐☐☐ Quantity shipped?
- ☐☐☐ Manufacturer's name and lot number?

DRIC Initials _____

Yes No N/A

- ☐☐☐ Date of shipment?
- ☐☐☐ Name of the pharmacist or vet retailer exemptee who is responsible for the distribution?

☐☐☐ Are copies of the records of shipment (also known as the expanded invoice) distributed to the prescribing veterinarian? (CCR 1780.1 [i])

☐☐☐ Are copies of the records of shipment (also known as the expanded invoice) of labeled dangerous drugs retained by your business for 3years? (CCR 1780.1[I])

Inventory

Yes No N/A

☐☐☐ Is a current, accurate inventory maintained for all dangerous drugs (B&P 4081[a], CCR 1718)

Consultant Pharmacist

Yes No N/A

☐☐☐ Are consultant pharmacist semi-annual reports retained by your business for 3 years from the making? (B&P 4198 [e])

Quality Assurance

Yes No N/A

☐☐☐ Is quality assurance documentation retained for 3 years from the making? (B&P 4198[d])

Policies and Procedures

Yes No N/A

☐☐☐ Are all policies and procedures specified in section 4198(a) maintained for 3 years from the making? (B&P 4198(b)

☐☐☐ Are all policies and procedures, documents related to the quality assurance program, and all records of employee training and demonstrated competency open for inspection by authorized officers of the law? (B&P 4198[b])

Temporary removal of records

Yes No N/A

☐☐☐ If you temporarily remove purchase or sales records from your business, does your business retain, on your licensed premises at all times, a photocopy of each record temporarily removed? (B&P 4105[b])

DRIC Initials _____

Off-site storage waiver

Yes No N/A

☐☐☐ Are required records stored off-site only if a board issued written waiver has been granted? (CCR 1707[a])

☐☐☐ If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below: (CCR 1707[a])

_____

_____

Yes No N/A

☐☐☐ If an off-site written waiver is in place, is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐☐☐ If an off-site waiver is in place, are the records stored off-site retrievable within 2 business days? (1707[b][1])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

19. Reporting Requirements to the Board

Ownership

Yes No N/A

☐☐☐ I understand this veterinary retailer license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted, in addition to an application for a permanent new permit, to the board, if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval. (B&P 4201[h][I], 4196[b], CCR 1709[b])

☐☐☐ Are transfers, in a single transaction or a series of transactions, of 10% or more of the beneficial interest in a business licensed by the board to a person who did not hold beneficial ownership interest at the time of the initial permit was issued, reported in writing to the board within 30 days of the transaction? (CCR 1709[b])

☐☐☐ Any transfer of a beneficial interest in a business licensed by the board, in a single transaction or series of transactions, to a person or entity, which results in the transferee holding 50% or more shall constitute of change of ownership and an application must be submitted to the board for a change of ownership. (CCR 1709 [c])

DRIC Initials _____

Yes No N/A

☐☐☐ When called upon by an inspector, can the business owner or manager, produce information indicating the names of the business owners, managers and employees and a brief statement of the capacity for each person employed by the business? (B&P 4082)

Veterinarian

Yes No N/A

☐☐☐ Whenever a veterinary designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, or extra label use drugs prescribed by multiple veterinarians, does the veterinary designated representative contact the prescribing veterinarians for authorization before dispensing any drugs? (CCR 1780.1[f])

☐☐☐ Are copies of expanded invoices, documenting sales of dangerous drugs, distributed to the prescribing veterinarian within 72 hours of dispensing? (CCR 1780.1[I]).

☐☐☐ Is a written copy of any oral prescription received by either a pharmacist or designated representative of the veterinary food-animal drug retailer sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

Consultant Pharmacist

Yes No N/A

☐☐☐ Does the consultant pharmacist provide written certification every 6 months that your business is or is not in compliance with all applicable statutes and regulation? (B&P 4198[e])

☐☐☐ Does your business submit the most recent consultant pharmacist report with the annual application to renew the veterinary food-animal drug retailer license with this board? (B&P 4198[e])

Designated Representative in Charge/ Designated Representative

Yes No N/A

☐☐☐ If a designated representative-in-charge terminates employment at this business, does the business notify the board within 30 days of the termination? (B&P 4101[b], 4305.5[c])

☐☐☐ When a veterinary designated representative leaves the employ of a veterinary food-animal drug retailer, would the business owner immediately return the exemptee license to the Board of Pharmacy? (CCR 1780.1[I])

☐☐☐ When a designated representative in charge terminates employment at this business, does the designated representative in charge notify the board within 30 days of the termination.? This requirement is in addition to the requirement for the owner to notify this board. (B&P 4101[c])

DRIC Initials _____

Discontinuation of Business

Yes No N/A

☐☐☐ I understand if this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business? (CCR 1708.2).

☐☐☐ I understand the owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs? (CCR 1705)

Controlled substances (if applicable)

Yes No N/A

☐☐☐ Does the owner report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs? (CCR 1715.6)

☐☐☐ Does the owner notify the DEA, on a DEA form 106, of any theft or significant loss of controlled substances upon discovery? (CFR 1301.74[c])

☐☐☐ Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

Yes No N/A

☐☐☐ If the business holds a DEA registration, does the owner understand the requirement to notify the DEA promptly of the discontinuation of the business and all unused DEA 222 order forms must be returned to the DEA? (CFR1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN_____

_____

20. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesaler licenses held in other states, permits or licenses required by foreign countries or other entities (B&P 4107, 4059[a], CFR 1305.11[a])

_____

_____

_____

DRIC Initials _____

Designated Representative-in-Charge/Pharmacist Certification:

DESIGNATED REPRESENTATIVE-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this veterinary food-animal drug retailer of which I am the designated representative-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Designated Representative-In-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&P], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

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California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
Phone: (888) 539-3370
Fax: 877-508-6704

Bureau of Narcotic Enforcement
Security Prescription and CURES Programs
1102 Q Street, 6th Fl.
Sacramento, CA 95817
(916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

PRESCRIBER BOARDS:

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
Fax: (916) 263-2387
http://www.mbc.ca.gov

Dental Board of California
1432 Howe Ave. #85
Sacramento, CA 95825
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
2720 Gateway Oaks Drive, #350
Sacramento, CA 95833
(916) 263-3100
fax: (916) 263-3117
http://www.ombc.ca.gov

Physician Assistant Committee
1424 Howe Avenue, #35
Sacramento, CA 95825
(916) 561-8780
fax: (916) 263-2671
http://www.physicianassistant.ca.gov

Board of Podiatric Medicine
1420 Howe Avenue, #8
Sacramento, CA 95825
(800) 633-2322
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
1420 Howe Avenue, #6
Sacramento, CA 95825
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

FEDERAL AGENCIES:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov

Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):
(800) 882-9539

Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp

Online DEA 222 Controlled Substance Ordering System (CSOS):
http://www.deaecom.gov/

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(888) 415-9822 or (213) 621-6960 (Registration)
(213) 621-6942 or 6952
(Diversion or Investigation)

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: (909) 328-6000 or
(909) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (916) 480-7100 or
(916) 480-7250

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

Board of Pharmacy
Specific Language to Add Section 1751.8

Add Section 1751.8 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1, shall provide evidence satisfactory to the board that:
  (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.
  (2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standard-setting organizations.
  (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.
  (4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).
  (5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.

(c) The board shall consider the length of time the agency has been operating as an accrediting agency.

(d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.

(e) On an annual basis, no later than July 1 of each year, an approved accrediting agency will submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.

(f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an

approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Board of Pharmacy
Specific Language

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Under Development

1. Proposed Amendment to 16 CCR §1780 – Update the USP Standards Reference Material

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

President Schell and Committee Chair Bob Graul are serving in the subcommittee and will be working with board staff and industry.

2. Proposed Amendment to 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically,

committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: January 5, 2009

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
Reintroduction of 2008 Omnibus Provisions

At the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. Many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

These omnibus provisions were categorized into four types of changes:

1. Use of mobile pharmacies.
2. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.
3. General omnibus provisions.
4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

Below is a summary of the changes by category and section.

Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Pharmacist-in-Charge and Designated Representative-in-Charge

Consistent with the board's strategic objective 3.3, board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge (PIC) as well as a designated representative-in-charge (DRIC). As a result of this review, several omnibus changes were recommended to include some technical changes as well as refine the definitions of the pharmacist-in-charge and designated representative-in-charge and clarify the reporting requirements when a change of PIC or DRIC occurs. These changes were approved by the board and many were incorporated in SB 1779 as omnibus provisions. This bill was vetoed by the Governor. Board staff recommends that the board again consider including these changes as omnibus provisions in 2009.

Below is a list of the specific recommended changes as well as a brief statement about the specific proposed changes. The proposed language is following this memo.

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
  This section requires amendment to clarify the definition of "designated representative-in-charge" as well as the responsibilities of a licensee serving as such.

- Section 4036.5 – Pharmacist-in-Charge
  A new section is needed to define the term "pharmacist-in-charge" as well as the responsibilities a pharmacist serving as such.

- Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.
  This section requires amendment to clarify when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she ceased to serve in such a capacity.

- Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
  This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition, this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days as required.

- Section 4160 – Wholesaler Licenses
  This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

- Section 4161 – Non-Resident Wholesaler; Requirements
  This section requires amendment to further clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC 4043.

- Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked
  This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

- Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
  This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

- Section 4329 – Nonpharmacists; Prohibited Acts
  This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

- Section 4330 – Proprietors; Prohibited Acts

This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

General Omnibus Provisions

In addition to the changes listed above all of the following proposals were also approved as omnibus provisions for 2008.

- Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions.
  A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

- Section 4081 – Records of Dangerous Drugs or Devices Kept Open for Inspection ; Maintenance of Records, Current Inventory
  This section requires amendment to replace the term representative-in-charge with "designated representative-in-charge."

- Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
  This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

- Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
  This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation initiated by the board.

- Section 4362 – Entry Into Pharmacists Recovery Program
  This section requires amendment to specify the administrative co-pay participants pay.

- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
  This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

Omnibus Provisions Resulting from Recodification of Business and Professions Code §4052.

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following B&PC sections and H&SC section reference 4052 and require technical updates.

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facililty – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership

- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

Following is language previously approved by the board that board staff will submit to the Senate Business and Professions Committee for inclusion in this year's omnibus bill. While board staff does not anticipate any opposition, should it occur, board members will be advised.

Business and Professions Code Amendments

§ 733. Dispensing Prescription Drugs and Devices

(a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate' s objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) The provisions of this section shall apply to the drug therapy described in paragraph (8) of subdivision (a) of Section ~~4052~~ 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third party payer accepted by the licentiate or payment of any required copayment by the patient.

§ 4022.5. Designated representative; designated representative-in-charge

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties in Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board ~~who is~~ as the supervisor or manager ~~of a~~ responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

§ 4027. Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities

(a) As used in this chapter, the terms "skilled nursing facility," "intermediate care facility," and other references to health facilities shall be construed with respect to the definitions contained in Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code.

(b) As used in paragraph (4) of subdivision (a) of Section ~~4052~~ 4052.1, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in paragraph (5) of subdivision (a) of Section ~~4052~~ 4052.2, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of Health Services pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

§ 4036.5. Pharmacist-in-charge

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

§ 4040. Prescription; Content Requirements

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

§ 4051. Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section ~~4052~~ 4052.2, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

§ 4059.5. Who may order dangerous drugs or devices, exceptions

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the~~ a designated representative ~~may~~ must sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the

state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall become operative on January 1, 2006.

§ 4060. Controlled Substance – Prescription Required, Exceptions

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer. Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

§ 4062. Furnishing Dangerous Drugs During and Emergency

(a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or

device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) Except as otherwise provide in Section 4110, during a declared federal, state, or local emergency the board will allow for the deployment of a mobile pharmacy to impacted areas to ensure the continuity of patient care if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing;

(2) The mobile pharmacy retains records of dispensing as required in subdivision (a);

(3) A licensed pharmacist is on the premises, and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed;

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy;

(5) The mobile pharmacy is located within the declared disaster area or affected areas; and

(6) The mobile pharmacy ceases the provisions of services within forty-eight (48) hours following the termination of the declared emergency.

§ 4076. Prescription Container – Requirements for Labeling

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol ~~pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
(7) The strength of the drug or drugs dispensed.
(8) The quantity of the drug or drugs dispensed.
(9) The expiration date of the effectiveness of the drug dispensed.
(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.
(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:
(i) Prescriptions dispensed by a veterinarian.
(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
(iii) Dispensed medications for which no physical description exists in any commercially available database.
(B) This paragraph applies to outpatient pharmacies only.
(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

§ 4081. Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized

officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

§ 4101. ~~Persons in charge of pharmacy or exemptees~~ Pharmacist-in-charge; designated representative-in-charge; termination of ~~employment~~ status; duty to notify board

(a) A pharmacist ~~who takes~~ may take charge of~~, or acts~~ and act as the pharmacist-in-charge of a pharmacy ~~or other entity licensed by the board~~ upon application by the pharmacy and approval by the board. Any pharmacist-in-charge who ~~terminates his or her employment at the pharmacy~~ ceases to act as the pharmacist-in-charge of the pharmacy ~~or other entity~~, shall notify the board in writing within 30 days of the ~~termination of employment~~ date of such change in status.

(b) ~~An exemptee~~ A designated representative or a pharmacist may take charge of and act as the designated representative-in-charge of a wholesaler or veterinary food drug-animal retailer upon application by the wholesaler or veterinary food drug-animal retailer and approval by the board. Any designated representative-in-charge who ~~terminates his or her employment~~ ceases to act as the designated representative-in-charge at that entity, shall notify the board in writing within 30 days of the ~~termination of employment~~ date of such change in status.

§ 4110 License Required, Temporary Permit Upon Transfer of Ownership

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.
(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to

conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy, when a pharmacy is destroyed or damaged, under construction, or being remodeled and when needed to protect the health and safety of the public and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the Pharmacits-in-Charge of the pharmacy that was destroyed or damaged.

(3) A licensed pharmacist is on the premises while drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction or damage and an expected restoration date.

(6) Within three (3) calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration to the permanent pharmacy.

(7) The mobile pharmacy is not operated for more than forty-eight (48) hours following the restoration of the pharmacy.

§ 4111. Restrictions on Prescriber Ownership

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section ~~4052~~ 4052.2.

§ 4113. Pharmacists-in-charge; ~~designation~~ approval; responsibilities; notifications

(a) Every pharmacy shall ~~designate a pharmacist-in-charge and within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated~~ be supervised or managed by a pharmacist-in-charge. As part of its initial application for a license, and for each renewal, each pharmacy shall, on a form designed by the board, provide identifying information and the California license number for a pharmacist proposed to serve as the pharmacist-in-charge. The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a ~~pharmacist ceases to be a~~ pharmacist-in-charge ceases to act as pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(d) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead supply on that form the name of any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge, with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

§ 4126.5. Persons or organizations that pharmacies may furnish with dangerous drugs; violations; offset of amounts due; definitions

(a) A pharmacy may furnish dangerous drugs only to the following, and only the following may receive dangerous drugs furnished by a pharmacy:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section ~~by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities~~ may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

§ 4160. Wholesaler Licenses

(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) ~~The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative.~~ Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler.

(e) ~~A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.~~ Every wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(e f) A drug manufacturer licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(~~f~~ g) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be ~~five hundred fifty dollars ($550)~~ six hundred dollars ($600) ~~or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products~~. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

~~(g) This section shall become operative on January 1, 2006.~~

§ 4161. Out-of-State Distributor; Requirements

(a) A person located outside this state that *(1)* ships, *sells,* mails, or delivers dangerous drugs or dangerous devices into this state *or (2) sells, brokers, or distributes dangerous drugs or devices within this state* shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, *selling,* mailing, or delivering dangerous drugs or dangerous devices to a site located in this state *or selling, brokering, or distributing dangerous drugs or devices within this state* .
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, *sold,* mailed, or delivered to a site located in this state *or sold, brokered, or distributed within this state*. A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

§ 4174. Dispensing by Pharmacist Upon Order of a Nurse Practitioner

Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section ~~4052~~ 4052.2.

§ 4196. Veterinary Food-Animal Drug Retailer Licenses; persons allowed in areas where drugs stored, possessed, or repacked

(a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) ~~The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative.~~ Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each renewal, each veterinary food-animal drug retailer shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.

(e) ~~Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.~~ Every veterinary food-animal drug retailer shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge who ceases to act as designated

pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

(c) A pharmacist or intern pharmacist enrolled in the pharmacists recovery program shall be responsible to pay an administrative co-pay of $125 monthly to cover a portion of the administrative costs borne by the board to contract for these services. This fee may be waived, reduced, or deferred by the board or its designee if the participant demonstrates a financial hardship.

Health and Safety Code Amendment

§ 11150 – Persons Authorized to Write or Issue a Prescription

No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nursemidwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

§ 11165. Controlled Substance Utilization Review and Evaluation System: Establishment; Operations; Funding; Reporting to Legislature

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's

Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:
(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(3) Pharmacy prescription number, license number, and federal controlled substance registration number.
(4) NDC (National Drug Code) number of the controlled substance dispensed.
(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Number of refills ordered.
(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
(9) Date of origin of the prescription.
(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: January 5, 2009

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
Omnibus Provisions for 2009

At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions.

Add Section 4146 – Disposal of Returned Sharps by a Pharmacy
This section needs to be added to allow a pharmacy to accept returned sharps containers from consumers for disposal.

Add Section 4013 – Subscriber Alert
This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Amend Section 4401 – Pharmacists: Biennial Renewal
This section needs amendment to require pharmacists to notify the board of any misdemeanor or felony conviction, or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

Amend Section 4403 – Reissuance Without Payment of Fees Prohibited
This section needs amendment to require pharmacy technicians and designated representatives to notify the board of any misdemeanor or felony conviction, or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

Following is language that will be submitted to the Senate Business and Professions Committee for inclusion in the omnibus bill. While we do not anticipate any opposition to these provisions, should any arise, board members will be advised.

Proposed New Omnibus Provisions

4146. Disposal of Sharps Containers

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code Section 117750.

4013 Subscriber Alert

(a) By July 1, 2010 all board licensed facilities must join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.
(b) After July 1, 2010, any facility licensed by the board must update their e-mail address with the board's e-mail notification list within 30 days when a change in the e-mail address occurs.

4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.
(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. ~~All nonresident pharmacies shall register with the board~~. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.
(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.
(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.
(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.
(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section
4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.
(h) The registration fee shall be the fee specified in subdivision (a) of Section 4400.
(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.
(j) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

4401. Pharmacist: Biennial Renewal

(a) Every pharmacist who desires to retain his or her license on the books of the board shall biennially pay to the executive officer of the board the renewal fee, established by the board, within the limits prescribed by this chapter. In return for the payment of the renewal fee, a certificate of renewal shall be issued.
(b) As part of the renewal, a pharmacist must notify the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the licensee's last renewal.

4403. Reissuance Without Payment of Fees Prohibited

(a) The board shall not reissue or renew any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.
(b) As part of the renewal, a pharmacy technician must notify the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the licensee's last renewal.
(c) As part of the renewal, a designated representative must notify the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the licensee's last renewal.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: January 5, 2009

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
Immunization Proposal – Amendment to Business and Professions Code Section 4052 and Section 4052.8

At the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Beginning in November 2007, board staff worked with stakeholders to address questions as well as to elicit support for this proposal for sponsorship in 2008. However, in April 2008, after consideration it was decided not to move the proposal last year due to a lack of staff and other legislative priorities.

Board staff is contacting potential authors for this proposal and will resume stakeholder meetings in February 2009 to solidify a broad base of support for this proposal.

Following is a copy of the proposed language as well as a copy of the ACIP Adult and Adolescent Immunization Schedules.

Proposal to Amend B&PC 4052

§4052 – Furnishing to a Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

2) Transmit a valid prescription to another pharmacist.

3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

9) Initiate and administer immunizations ~~pursuant to a protocol with a prescriber~~ as authorized by Section 4052.8.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

4052.8 (a) A pharmacist may initiate and administer immunizations pursuant to a protocol with a prescriber. A pharmacist may also initiate and administer immunizations pursuant to the current Recommended Adult (19+ years) and Adolescent (7-18 years) Immunization Schedules, provided by the Centers for Disease Control and Prevention (CDC) pursuant to published recommendations of the CDC Advisory Committee on Immunization Practices (ACIP).

(b) Prior to initiating and administering an immunization pursuant to this section, a pharmacist shall have completed the American Pharmacists Association pharmacy-based immunization certificate program or another pharmacy-based immunization training certificate program endorsed by the Centers for Disease Control and Prevention or the American Council of Pharmaceutical Education.
(c) A pharmacist initiating and administering any immunization pursuant to this section shall also complete 3 hours of immunization-related continuing education coursework annually. Failure at any time to meet this requirement shall, in addition to any other sanctions, require the pharmacist to re-take the training identified in subdivision (b) prior to administration of any further immunization(s).
(d) A pharmacist shall at all times maintain current Basic Life Support certification.
(e) At the time of administration of an immunization, the pharmacist shall:

(1) Provide the patient or patient's agent with the appropriate Vaccine Information Statement for each immunization administered; and
(2) Provide documentation of administration of the immunization to the patient and patient's physician or primary care provider, if one can be identified.

(f) Any pharmacist initiating and administering vaccines pursuant to this section may initiate and administer epinephrine by injection for severe allergic reactions.
(g) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.
(h) The pharmacist shall maintain an immunization administration record, which includes, but is not limited to, the name of the vaccine, expiration date, date of administration, manufacturer and lot number, administration site and route, Vaccine Information Statement date, and the name and title of the person administering, for the longer of the following periods:

(1) Ten years from the date of administration; or
(2) If less than 18 years at the time of administration, three years beyond the patient's eighteenth birthday.

(i) Upon receipt of a vaccine as authorized by this section, a pharmacist is responsible to assure that proper vaccine temperatures are maintained during subsequent storage and handling to preserve potency.

Recommended Immunization Schedule for Persons Aged 7–18 Years—UNITED STATES • 2007

Vaccine ▼ / Age ▶	7–10 years	11–12 YEARS	13–14 years	15 years	16–18 years
Tetanus, Diphtheria, Pertussis[1]	see footnote 1	Tdap	Tdap		
Human Papillomavirus[2]	see footnote 2	HPV (3 doses)	HPV Series		
Meningococcal[3]	MPSV4	MCV4	MCV4[3] MCV4		
Pneumococcal[4]	PPV				
Influenza[5]	Influenza (Yearly)				
Hepatitis A[6]	HepA Series				
Hepatitis B[7]	HepB Series				
Inactivated Poliovirus[8]	IPV Series				
Measles, Mumps, Rubella[9]	MMR Series				
Varicella[10]	Varicella Series				

Range of recommended ages

Catch-up immunization

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2006, for children aged 7–18 years. Additional information is available at **http://www.cdc.gov/nip/recs/child-schedule.htm.** Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at **http://www.vaers.hhs.gov** or by telephone, **800-822-7967.**

1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).
(Minimum age: 10 years for BOOSTRIX® and 11 years for ADACEL™)
- Administer at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoids vaccine (Td) booster dose.
- Adolescents aged 13–18 years who missed the 11–12 year Td/Tdap booster dose should also receive a single dose of Tdap if they have completed the recommended childhood DTP/DTaP vaccination series.

2. Human papillomavirus vaccine (HPV). *(Minimum age: 9 years)*
- Administer the first dose of the HPV vaccine series to females at age 11–12 years.
- Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose.
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

3. Meningococcal vaccine. *(Minimum age: 11 years for meningococcal conjugate vaccine [MCV4]; 2 years for meningococcal polysaccharide vaccine [MPSV4])*
- Administer MCV4 at age 11–12 years and to previously unvaccinated adolescents at high school entry (at approximately age 15 years).
- Administer MCV4 to previously unvaccinated college freshmen living in dormitories; MPSV4 is an acceptable alternative.
- Vaccination against invasive meningococcal disease is recommended for children and adolescents aged ≥2 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups. See *MMWR* 2005;54(No. RR-7):1–21. Use MPSV4 for children aged 2–10 years and MCV4 or MPSV4 for older children.

4. Pneumococcal polysaccharide vaccine (PPV). *(Minimum age: 2 years)*
- Administer for certain high-risk groups. See *MMWR* 1997;46(No. RR-8):1–24, and *MMWR* 2000;49(No. RR-9):1–35.

5. Influenza vaccine. *(Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 5 years for live, attenuated influenza vaccine [LAIV])*
- Influenza vaccine is recommended annually for persons with certain risk factors, health-care workers, and other persons (including household members) in close contact with persons in groups at high risk. See *MMWR* 2006;55 (No. RR-10):1–41.
- For healthy persons aged 5–49 years, LAIV may be used as an alternative to TIV.
- Children aged <9 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by ≥4 weeks for TIV and ≥6 weeks for LAIV).

6. Hepatitis A vaccine (HepA). *(Minimum age: 12 months)*
- The 2 doses in the series should be administered at least 6 months apart.
- HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children. See *MMWR* 2006;55 (No. RR-7):1–23.

7. Hepatitis B vaccine (HepB). *(Minimum age: birth)*
- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11–15 years.

8. Inactivated poliovirus vaccine (IPV). *(Minimum age: 6 weeks)*
- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age ≥4 years.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

9. Measles, mumps, and rubella vaccine (MMR). *(Minimum age: 12 months)*
- If not previously vaccinated, administer 2 doses of MMR during any visit, with ≥4 weeks between the doses.

10. Varicella vaccine. *(Minimum age: 12 months)*
- Administer 2 doses of varicella vaccine to persons without evidence of immunity.
- Administer 2 doses of varicella vaccine to persons aged <13 years at least 3 months apart. Do not repeat the second dose, if administered ≥28 days after the first dose.
- Administer 2 doses of varicella vaccine to persons aged ≥13 years at least 4 weeks apart.

The Recommended Immunization Schedules for Persons Aged 0–18 Years are approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/nip/acip), the American Academy of Pediatrics (http://www.aap.org), and the American Academy of Family Physicians (http://www.aafp.org).

Catch-up Immunization Schedule for Persons Aged 4 Months–18 Years Who Start Late or Who Are More Than 1 Month Behind

UNITED STATES • 2007

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
CATCH-UP SCHEDULE FOR PERSONS AGED 4 MONTHS–6 YEARS					
Hepatitis B[1]	Birth	4 weeks	8 weeks (and 16 weeks after first dose)		
Rotavirus[2]	6 wks	4 weeks	4 weeks		
Diphtheria, Tetanus, Pertussis[3]	6 wks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[4]	6 wks	4 weeks if first dose administered at age <12 months 8 weeks (as final dose) if first dose administered at age 12-14 months No further doses needed if first dose administered at age ≥15 months	4 weeks[4] if current age <12 months 8 weeks (as final dose)[4] if current age ≥12 months and second dose administered at age <15 months No further doses needed if previous dose administered at age ≥15 months	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Pneumococcal[5]	6 wks	4 weeks if first dose administered at age <12 months and current age <24 months 8 weeks (as final dose) if first dose administered at age ≥12 months or current age 24–59 months No further doses needed for healthy children if first dose administered at age ≥24 months	4 weeks if current age <12 months 8 weeks (as final dose) if current age ≥12 months No further doses needed for healthy children if previous dose administered at age ≥24 months	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	4 weeks[6]	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	3 months			
Hepatitis A[9]	12 mos	6 months			
CATCH-UP SCHEDULE FOR PERSONS AGED 7–18 YEARS					
Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis[10]	7 yrs[10]	4 weeks	8 weeks if first dose administered at age <12 months 6 months if first dose administered at age ≥12 months	6 months if first dose administered at age <12 months	
Human Papillomavirus[11]	9 yrs	4 weeks	12 weeks		
Hepatitis A[9]	12 mos	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and 16 weeks after first dose)		
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	4 weeks[6]	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	4 weeks if first dose administered at age ≥13 years 3 months if first dose administered at age <13 years			

1. Hepatitis B vaccine (HepB). *(Minimum age: birth)*
- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11–15 years.

2. Rotavirus vaccine (Rota). *(Minimum age: 6 weeks)*
- Do not start the series later than age 12 weeks.
- Administer the final dose in the series by age 32 weeks. Do not administer a dose later than age 32 weeks.
- Data on safety and efficacy outside of these age ranges are insufficient.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). *(Minimum age: 6 weeks)*
- The fifth dose is not necessary if the fourth dose was administered at age ≥4 years.
- DTaP is not indicated for persons aged ≥7 years.

4. *Haemophilus influenzae* type b conjugate vaccine (Hib). *(Minimum age: 6 weeks)*
- Vaccine is not generally recommended for children aged ≥5 years.
- If current age <12 months and the first 2 doses were PRP-OMP (PedvaxHIB® or ComVax® [Merck]), the third (and final) dose should be administered at age 12– 15 months and at least 8 weeks after the second dose.
- If first dose was administered at age 7–11 months, administer 2 doses separated by 4 weeks plus a booster at age 12–15 months.

5. Pneumococcal conjugate vaccine (PCV). *(Minimum age: 6 weeks)*
- Vaccine is not generally recommended for children aged ≥5 years.

6. Inactivated poliovirus vaccine (IPV). *(Minimum age: 6 weeks)*
- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if third dose was administered at age ≥4 years.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

7. Measles, mumps, and rubella vaccine (MMR). *(Minimum age: 12 months)*
- The second dose of MMR is recommended routinely at age 4–6 years but may be administered earlier if desired.
- If not previously vaccinated, administer 2 doses of MMR during any visit with ≥4 weeks between the doses.

8. Varicella vaccine. *(Minimum age: 12 months)*
- The second dose of varicella vaccine is recommended routinely at age 4–6 years but may be administered earlier if desired.
- Do not repeat the second dose in persons aged <13 years if administered ≥28 days after the first dose.

9. Hepatitis A vaccine (HepA). *(Minimum age: 12 months)*
- HepA is recommended for certain groups of children, including in areas where vaccination programs target older children. See *MMWR* 2006;55(No. RR-7):1–23.

10. Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap). *(Minimum ages: 7 years for Td, 10 years for BOOSTRIX®, and 11 years for ADACEL™)*
- Tdap should be substituted for a single dose of Td in the primary catch-up series or as a booster if age appropriate; use Td for other doses.
- A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose. A booster (fourth) dose is needed if any of the previous doses were administered at age <12 months. Refer to ACIP recommendations for further information. See *MMWR* 2006;55(No. RR-3).

11. Human papillomavirus vaccine (HPV). *(Minimum age: 9 years)*
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

Information about reporting reactions after immunization is available online at **http://www.vaers.hhs.gov** or by telephone via the 24-hour national toll-free information line 800-822-7967. Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for immunization, is available from the National Center for Immunization and Respiratory Diseases at **http://www.cdc.gov/nip/default.htm** or telephone, **800-CDC-INFO (800-232-4636)**.

FIGURE 1. Recommended adult immunization schedule, by vaccine and age group — United States, October 2007–September 2008

Vaccine	Age group (yrs) 19–49	50–64	≥65
Tetanus, diphtheria, pertussis (Td/Tdap)[1]*	1-dose Td booster every 10 yrs; Substitute 1 dose of Tdap for Td		
Human papillomavirus (HPV)[2]*	3 doses (females) (0, 2, 6 mos)		
Measles, mumps, rubella (MMR)[3]*	1 or 2 doses	1 dose	
Varicella[4]*	2 doses (0, 4–8 wks)		
Influenza[5]*	1 dose annually	1 dose annually	
Pneumococcal (polysaccharide)[6,7]	1–2 doses		1 dose
Hepatitis A[8]*	2 doses (0, 6–12 mos or 0, 6–18 mos)		
Hepatitis B[9]*	3 doses (0, 1–2, 4–6 mos)		
Meningococcal[10]*	1 or more doses		
Zoster[11]			1 dose

* Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

NOTE: These recommendations must be read along with the footnotes, which are on pages Q2–Q4 of this schedule.

Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians. Complete statements from ACIP are available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.

1. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination

Tdap should replace a single dose of Td for adults aged <65 years who have not previously received a dose of Tdap. Only one of two Tdap products (Adacel® [Sanofi Pasteur]) is licensed for use in adults.

Adults with uncertain histories of a complete primary vaccination series with tetanus and diphtheria toxoid–containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus and diphtheria toxoid–containing vaccines; administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. However, Tdap can substitute for any one of the doses of Td in the 3-dose primary series. The booster dose of tetanus and diphtheria toxoid–containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received ≥10 years previously. Tdap or Td vaccine may be used, as indicated.

If the person is pregnant and received the last Td vaccination ≥10 years previously, administer Td during the second or third trimester; if the person received the last Td vaccination in <10 years, administer Tdap during the immediate postpartum period. A one-time administration of 1 dose of Tdap with an interval as short as 2 years from a previous Td vaccination is recommended for postpartum women, close contacts of infants aged <12 months, and all health-care workers with direct patient contact. In certain situations, Td can be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap can be administered instead of Td to a pregnant woman after an informed discussion with the woman.

Consult the ACIP statement for recommendations for administering Td as prophylaxis in wound management.

2. Human papillomavirus (HPV) vaccination

HPV vaccination is recommended for all females aged ≤26 years who have not completed the vaccine series. History of genital warts, abnormal Papanicolaou test, or positive HPV DNA test is not evidence of prior infection with all vaccine HPV types; HPV vaccination is still recommended for these persons.

Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, females who are sexually active should still be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types receive the full benefit of the vaccination. Vaccination is less beneficial for females who have already been infected with one or more of the HPV vaccine types.

A complete series consists of 3 doses. The second dose should be administered 2 months after the first dose; the third dose should be administered 6 months after the first dose.

Although HPV vaccination is not specifically recommended for females with the medical indications described in Figure 2, "Vaccines that might be indicated for adults based on medical and other indications," it is not a live-virus vaccine and can be administered. However, immune response and vaccine efficacy might be less than in persons who do not have the medical indications described or who are immunocompetent.

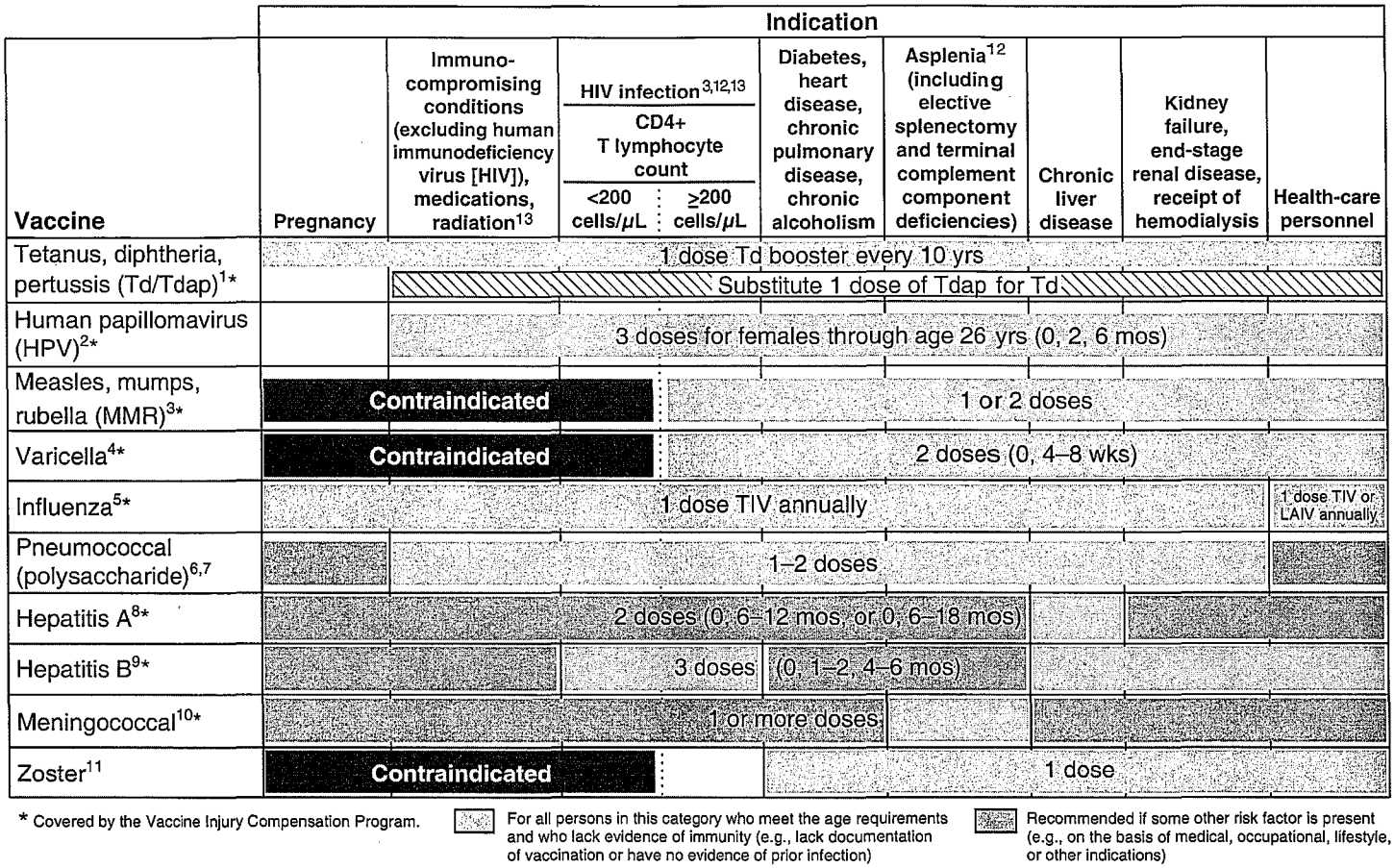
3. Measles, mumps, rubella (MMR) vaccination

Measles component: adults born before 1957 can be considered immune to measles. Adults born during or after 1957 should receive ≥1 dose of MMR unless they have a medical contraindication, documentation of ≥1 dose, history of measles based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or are in an outbreak setting; 2) have been previously vaccinated with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.

Mumps component: adults born before 1957 can generally be

FIGURE 2. Vaccines that might be indicated for adults based on medical and other indications — United States, October 2007–September 2008



* Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

considered immune to mumps. Adults born during or after 1957 should receive 1 dose of MMR unless they have a medical contraindication, history of mumps based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) are in an age group that is affected during a mumps outbreak; 2) are students in postsecondary educational institutions; 3) work in a health-care facility; or 4) plan to travel internationally. For unvaccinated health-care workers born before 1957 who do not have other evidence of mumps immunity, consider administering 1 dose on a routine basis and strongly consider administering a second dose during an outbreak.

Rubella component: administer 1 dose of MMR vaccine to women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity. For women of childbearing age, regardless of birth year, routinely determine rubella immunity and counsel women regarding congenital rubella syndrome. Women who do not have evidence of immunity should receive MMR vaccine on completion or termination of pregnancy and before discharge from the health-care facility.

4. Varicella vaccination

All adults without evidence of immunity to varicella should receive 2 doses of single-antigen varicella vaccine unless they have a medical contraindication. Special consideration should be given to those who 1) have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of immunocompromised persons) or 2) are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).

Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or presenting with an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link with a typical varicella case or to a laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on health-care provider diagnosis; or 5) laboratory evidence of immunity or laboratory confirmation of disease.

Assess pregnant women for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.

5. Influenza vaccination

Medical indications: chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus, renal or hepatic dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or human immunodeficiency virus [HIV]); any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, or seizure disorder or other neuromuscular disorder); and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia.

Occupational indications: health-care personnel and employees of long-term–care and assisted-living facilities.

Other indications: residents of nursing homes and other long-term–care and assisted-living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged 0–59 months, or persons of all ages with high-risk conditions); and anyone who would like to be vaccinated. Healthy, nonpregnant adults aged ≤49 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special care units can receive either intranasally administered live, attenuated influenza vaccine (FluMist®) or inactivated vaccine. Other persons should receive the inactivated vaccine.

6. Pneumococcal polysaccharide vaccination

Medical indications: chronic pulmonary disease (excluding asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver diseases, including liver disease as a result of alcohol abuse (e.g., cirrhosis); chronic alcoholism, chronic renal failure, or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]); immunosuppressive conditions; and cochlear implants and cerebrospinal fluid leaks. Vaccinate as close to HIV diagnosis as possible.

Other indications: Alaska Natives and certain American Indian populations and residents of nursing homes or other long-term–care facilities.

7. Revaccination with pneumococcal polysaccharide vaccine

One-time revaccination after 5 years for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); or immunosuppressive conditions. For persons aged ≥65 years, one-time revaccination if they were vaccinated ≥5 years previously and were aged <65 years at the time of primary vaccination.

8. Hepatitis A vaccination

Medical indications: persons with chronic liver disease and persons who receive clotting factor concentrates.

Behavioral indications: men who have sex with men and persons who use illegal drugs.

Occupational indications: persons working with hepatitis A virus (HAV)-infected primates or with HAV in a research laboratory setting.

Other indications: persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at http://wwwn.cdc.gov/travel/contentdiseases.aspx) and any person seeking protection from HAV infection.

Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix®), or 0 and 6–18 months (Vaqta®). If the combined hepatitis A and hepatitis B vaccine (Twinrix®) is used, administer 3 doses at 0, 1, and 6 months.

9. Hepatitis B vaccination

Medical indications: persons with end-stage renal disease, including patients receiving hemodialysis; persons seeking evaluation or treatment for a sexually transmitted disease (STD); persons with HIV infection; and persons with chronic liver disease.

Occupational indications: health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids.

Behavioral indications: sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); current or recent injection-drug users; and men who have sex with men.

Other indications: household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection; clients and staff members of institutions for persons with developmental disabilities; international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries is available at http://wwwn.cdc.gov/travel/contentdiseases.aspx); and any adult seeking protection from HBV infection.

Settings where hepatitis B vaccination is recommended for all adults: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential day care facilities for persons with developmental disabilities.

Special formulation indications: for adult patients receiving hemodialysis and other immunocompromised adults, 1 dose of 40 μg/mL (Recombivax HB®) or 2 doses of 20 μg/mL (Engerix-B®), administered simultaneously.

10. Meningococcal vaccination

Medical indications: adults with anatomic or functional asplenia or terminal complement component deficiencies.

Other indications: first-year college students living in dormitories; microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*; military recruits; and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa during the dry season [December–June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

Meningococcal conjugate vaccine is preferred for adults with any of the preceding indications who are aged ≤55 years, although meningococcal polysaccharide vaccine (MPSV4) is an acceptable alternative. Revaccination after 3–5 years might be indicated for adults previously vaccinated with MPSV4 who remain at increased risk for infection (e.g., persons residing in areas in which disease is epidemic).

11. Herpes zoster vaccination

A single dose of zoster vaccine is recommended for adults aged ≥60 years regardless of whether they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists for their condition.

12. Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used

Hib conjugate vaccines are licensed for children aged 6 weeks–71 months. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults with the chronic conditions associated with an increased risk for Hib disease. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had splenectomies; administering vaccine to these patients is not contraindicated.

13. Immunocompromising conditions

Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [trivalent inactivated influenza vaccine]) and live vaccines generally are avoided in persons with immune deficiencies or immune suppressive conditions. Information on specific conditions is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.

This schedule indicates the recommended age groups and medical indications for routine administration of currently licensed vaccines for persons aged ≥19 years, as of October 1, 2007. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or those issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (available at http://www.cdc.gov/vaccines/pubs/acip-list.htm).

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at http://www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at http://www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: January 5, 2009

To: Legislation and Regulation Committee

Subject: Legislation Sponsored by the Board of Pharmacy
Elements of a Prescription Label – Amendment to Business and Professions Code section 4076

At the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. This change will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. This proposal is consistent with the results of the board's prescription label survey where approximately 25% of all respondents requested the purpose of the medicine be included on the label.

Board staff is contacting potential authors for this proposal and is working the California Pharmacy Foundation.

Following is a suggested amendment that could achieve the desired outcome.

Proposal to Amend B&PC 4076

§4076 – Prescription Container – Requirements for Labeling

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The ~~condition~~ purpose for which the drug was prescribed if requested by the patient ~~and the condition is indicated on the prescription~~.

(11) (A) ~~Commencing January 1, 2006, t~~The physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: January 5, 2009

To: Legislation and Regulation Committee

From: Staff

Subject: Legislative Proposal Regarding the Return of Medicine to Reverse Distributors

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For several years, the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet.

Currently, the board is working with the California Integrated Waste Management Board along with several other state agencies and the California Department of Public Health on model programs for take back drugs. Model program guidelines were put in place December 1, 2008, as required by SB 966 (Simitian, Chapter 542, Statutes of 2007). The California Integrated Waste Management Board may make several amendments to these guidelines, possibly in February 2009. No amendments to the guidelines are currently available, although they may be by the time of the January 2009 Board Meeting.

In working with these agencies, there appears to be some confusion over when a licensed integrated waste hauler (licensed by the California Department of Public Health) and a licensed reverse distributor (licensed by the Board of Pharmacy) may pick up unsaleable medicine from a licensed or non-licensed facility.

In general, aggregate pharmaceutical waste, as occurs in take back programs whether operated by pharmacies or at community events where medicine is comingled/mixed with multiple drugs, needs to be handled up by licensed integrated waste haulers. Specifically, statutes enforced by CDPH require that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This includes all statutory requirements for storage and handling, and transportation.

Return of unsaleable drugs by a pharmacy or practitioner that have not been returned by patients is handled by a reverse distributor.

Pharmacies can return unwanted drugs (code sections referenced are on the attached pages):

- To the wholesaler from which it purchased the drugs (section 4126.5) This provision was created as part of the pedigree provisions, to prevent a pharmacy from acting as a wholesaler
- To a reverse distributor (a licensed wholesaler) if the drugs are unsaleable
- To an integrated waste hauler (for disposal) and for all drugs taken back by the pharmacy from patients

Staff has drafted proposed legislative changes to amplify this regulatory structure as indicated on the following pages.

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. Reverse distributors shall not accept the return of dangerous drugs that have been dispensed to patients that are later returned to the pharmacy or another licensed entity. Instead, dangerous drugs returned by a patient to a pharmacy, if accepted by the pharmacy, shall only be picked up or handled (if mailed) by a licensed integrated waste hauler.

For purposes of this section, "dispensed" means that the dangerous drugs have been provided to the patient or patient's agent, and taken from the pharmacy.

4043. (a) "Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not
store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.
~~(b) This section shall become operative January 1, 2006.~~

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:
(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
(3) A licensed wholesaler acting as a reverse distributor.
(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) Records of all dangerous drugs returned to a wholesaler or provided to a reverse distributor shall correctly document the date, name and address of the supplying pharmacy, the name and address of the wholesaler or reverse distributor, the drugs and the quantity of each drug returned. Records of all drugs returned to a licensed integrated waste hauler shall list the volume in weight or measurement of the pharmaceutical waste, the date and name of the pharmacy and the licensed waste hauler.

(c) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(~~c~~ d) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

~~(d) This section shall become operative on January 1, 2006.~~

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

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Although very early in the session, two bills were introduced impact the practice of pharmacy or the board's Jurisdiction

1. AB 67 (Nava) Pharmacy Patient Protection Act of 2008

This bill would establish the Pharmacy Patient Protection Act of 2008, which would require pharmacists to dispense all lawfully obtained prescriptions when the prescribed medication is in stock without regard to any ethical, moral, or religious objections.

2. SB 26 (Simitian) Home Generated Pharmaceutical Waste

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Following are copies of the bills and a brief analysis of each proposal. Board staff will be contacting the author's offices to obtain additional information.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

Bill No.:	**AB 67 (Nava)**
Version:	**Introduced 12/10/08**
Date of Analysis:	**January 5, 2009**

Existing Law:

Business and Professions Code section 733(b)(3) provides that a licentiate ***may*** decline to dispense a prescription drug or devise on ethical, moral, or religious grounds as defined.

This Bill:

This bill adds section 4052.6 to the Business and Professions Code. As introduced this bill provides that *irrespective of B&P 733(b)(3)* a pharmacist **shall** dispense each lawfully obtained prescription presented by a patient provided that the medication is in stock at the pharmacy in which the pharmacist is practicing.

A pharmacist's liberty of conscience, within the meaning of Section 4 of Article I of the California Constitution, shall not be grounds for a pharmacist to fail to dispense a prescription.

If a pharmacist fails to dispense a prescription pursuant to this Act, the patient or duly authorized representative may file a complaint with the board.

A violation of this provision shall be grounds for revocation of a pharmacist's license by the board.

This bill specifies that a notice describing the patient's rights pursuant to the Pharmacy Patient Protect Act of 2008 be posted, and prescribes information that is to be included.

History:
In 2006, Assembly member Nation sponsored legislation (AB 2583) to ensure that patients have access to their prescribed medications while preserving a licentiate's right to refuse to fill a prescription based on ethical, moral or religious reasons. While the legislation required the board's Notice to Consumers be amended to provide specified information, various committee analyses and discussions focused almost exclusively on a woman's access to emergency contraception (EC).

The bill quickly moved through the legislature and was signed by the Governor in September 2006 (Chapter 487, Statutes of 2006). As a result, the Board amended its Notice to Consumers and proposed regulations to effect the changes; regulations were formally approved by OAL in October 2007 and amended Notice to Consumers was issued.

FISCAL IMPACT

The board may receive increased complaints, as well as have an increase in disciplinary actions. Any minor impact could be absorbed with existing resources.

COMMENTS:

BOP staff will continue to work with the legal office to identify issues and seek clarification on the bill's impact to pharmacy law.

SUPPORT and OPPOSITION:

None known as of this date.

NOTICE TO CONSUMERS

KNOW YOUR RIGHTS

UNDER CALIFORNIA LAW CONCERNING MEDICINE AND DEVICES PRESCRIBED TO YOU.

YOU HAVE THE RIGHT TO RECEIVE MEDICINE AND DEVICES LEGALLY PRESCRIBED TO YOU, UNLESS:

1. The medicine or device is not in stock in the pharmacy.
2. The pharmacist, based upon his or her professional judgment determines providing the item:

   Is against the law, could cause a harmful drug interaction or could have a harmful effect on your health.

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely. The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

ANY QUESTIONS? ASK THE PHARMACIST!

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BE AWARE & TAKE CARE: Talk to your pharmacist!

NOTICE TO CONSUMERS

WHAT ARE YOU TAKING?

BEFORE TAKING ANY PRESCRIPTION MEDICINE, TALK TO YOUR PHARMACIST; BE SURE YOU KNOW THE FOLLOWING:

1. What is the name of the medicine and what does it do?
2. How and when do I take it—and for how long? What if I miss a dose?
3. What are the possible side effects and what should I do if they occur?
4. Will the new medicine work safely with other medicines and herbal supplements I am taking?
5. What foods, drinks or activities should I avoid while taking this medicine?

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone. Ask your pharmacist if a lower-cost generic drug is available to fill your prescription. Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

ASK YOUR PHARMACIST IF YOU HAVE ADDITIONAL QUESTIONS.

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BE AWARE & TAKE CARE: Talk to your pharmacist!

ASSEMBLY BILL No. 67

Introduced by Assembly Member Nava

December 10, 2008

An act to add Section 4052.6 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 67, as introduced, Nava. Pharmacy Patient Protection Act of 2008.

Existing law, the Unruh Civil Rights Act, provides that all persons are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, marital status, or sexual orientation and are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments.

Existing law, the Pharmacy Law, the knowing violation of which is a crime, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy in the Department of Consumer Affairs. Existing law prohibits pharmacists and other health care licentiates from obstructing a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient, except if the licentiate refuses on ethical, moral, or religious grounds and otherwise, as specified. Existing law provides that a violation of this prohibition constitutes unprofessional conduct and shall subject the pharmacist or other health care licentiate to disciplinary or administrative action by his or her licensing agency. Existing law authorizes the Board of Pharmacy to impose disciplinary

actions including suspension and revocation of a pharmacist's license, as specified.

This bill would establish the Pharmacy Patient Protection Act of 2008, which would require pharmacists to dispense all lawfully obtained prescriptions when the prescribed medication is in stock without regard to any ethical, moral, or religious objections.

This bill would provide that a pharmacist's failure to dispense a prescription as required would be grounds for revocation of the pharmacist's license.

Existing law requires pharmacies to post prominently a notice describing a patient's rights to obtain a prescription drug or device without obstruction by a pharmacist with exceptions and providing additional information, as specified. Existing law permits a pharmacy to provide the patient a written receipt containing the information required on the notice in lieu of posting a notice.

This bill would require a pharmacy to prominently display a sign explaining the patient's rights established by this bill, including the telephone number and Internet Web site for patients to utilize in filing a complaint.

This bill would make specified findings and declarations of the Legislature.

Because this bill would impose new requirements and prohibitions under the Pharmacy Law, the knowing violation of which would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. This act shall be known, and may be cited, as the Pharmacy Patient Protection Act of 2008.

SEC. 2. (a) The Legislature finds and declares that the California Supreme Court held in Benitez v. North Coast Women's Care Medical Group (2008) 44 Cal. 4th 1145, that the physicians' constitutional rights to free speech and free exercise of religion

afforded by the First Amendment to the United States Constitution did not exempt the physicians from complying with the Unruh Civil Rights Act (Sections 51 to 53, inclusive, of Civil Code. The court further held that the liberty of conscience provided in Section 4 of Article I of the California Constitution was insufficient to allow the physicians to engage in sexual orientation discrimination. The court held that the Unruh Civil Rights Act furthered a compelling interest in ensuring full and equal access to medical treatment irrespective of sexual orientation, and there were no less restrictive means to achieve that goal.

(b) The Legislature finds and declares that the state has a compelling interest in ensuring full and equal access to dispensed prescriptions and that interference with full and equal access to dispensed prescriptions is inconsistent with the safety of the state.

(c) The Legislature intends to apply the principles of this case law to dispensing of prescriptions by pharmacists to further ensure all patients full and equal access to medical treatment irrespective of sexual orientation, or otherwise.

SEC. 3. Section 4052.6 is added to the Business and Professions Code, to read:

4052.6. (a) Notwithstanding paragraph (3) of subdivision (b) of Section 733, a pharmacist shall dispense each lawfully obtained prescription presented by a patient provided that the prescribed medication is in stock at the pharmacy in which the pharmacist is practicing. A pharmacist shall dispense prescriptions irrespective of the pharmacist's ethical, moral, or religious objections. The liberty of conscience, within the meaning of Section 4 of Article I of the California Constitution, shall not be lawful grounds for a pharmacist to fail to dispense a prescription.

(b) If a pharmacist fails to dispense a prescription pursuant to subdivision (a), the patient named on the prescription, or his or her duly authorized representative, may file a complaint with the board in connection with the pharmacist's failure to dispense the prescription.

(c) A violation of subdivision (a) shall be grounds for revocation of a pharmacist's license by the board.

(d) Every pharmacy that is open to the public shall prominently display a notice explaining the patients' rights established pursuant to this section, including the telephone number and Internet Web site of the board for patients to utilize in filing a complaint. The

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

Bill No.:	**SB 26 (Simitian)**
Version:	**Introduced 12/1/08**
Date of Analysis:	**January 2, 2008**
Topic:	**Disposal of Pharmaceutical Wastes**

Analysis:

Board of Pharmacy

Pursuant to existing Pharmacy Law, the Board of Pharmacy oversees licensing, regulatory and disciplinary functions of the Board, and authorizes the Board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This Bill:

Requires the Board of Pharmacy to coordinate with other state agencies, local governments, etc., to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. To that end, SB 26

- **Adds** section 4001.2 to the Business and Professions Code, requiring the Board to coordinate with other state agencies, etc., to develop sustainable efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes.

- **Adds** section 4068.1 to the B&P Code authorizing a pharmacy to accept the return of home-generated pharmaceutical waste, as defined.

- **Adds** section 4146 to the B&P Code providing that a pharmacy may accept the return of home-generated sharps waste, as defined.

(continued)

Integrated Waste Management Board / Department of Public Health

Existing law provides that through the Integrated Waste Management Act of 1989, the Integrated Waste Management Board oversees, among other things, regulations that that set forth standards for solid waste management, including the collection and transportation of wastes. This bill also amends provisions which regulate the management and handling of medical waste, as defined, which fall under the authority of the California Department of Public Health.

This bill:

- Defines "common carrier" (adds section 117642 to the H&S Code)
- Defines "home-generated pharmaceutical waste (adds section 117669 to the H&S Code)
- Defines "pharmaceutical waste" (adds section 117748 to the H&S Code).
- Amends various Health and Safety code sections regarding medical waste management plans, collection, record keeping, hauling, transportation and destruction of specified wastes (H&S sections 117935.5, 117945, 117960, 118000, 118031, 118040, 118041, 118147, and 118165).
- Excludes home-generated pharmaceutical waste from the definition of "medical waste" (amends H&S Code section 11700(e)).
- Adds section 117904.5 to the H&S Code regarding the approval of a location as a point of consolidation for the collection of home-generated pharmaceutical waste. These points may include, but are not limited to: **pharmacies**, health care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, or government offices. This section provides that consolidation locations approved pursuant to this section shall be known as home-generated pharmaceutical waste consolidation points, and specifies that they are not subject to the permit requirements, or to any permit or registration fees. This section also specifies containers to be used for waste and other provisions related to the definition of generators of waste and requirements for tracking documents, as required.

FISCAL IMPACT

Unknown at this time.

COMMENTS:

Board staff will continue to work with the legal office to identify issues and seek clarification on the bill's impact to pharmacy law.

SUPPORT and OPPOSITION:

None known as of this date.

SENATE BILL No. 26

Introduced by Senator Simitian

December 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, 117935, 117945, 117960, 118000, 118040, 118147, and 118165 of, and to add Sections 117642, 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as introduced, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation of a disposal facility. The act requires the board to expend moneys from

the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by both hazardous waste haulers and common carriers, as defined. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4001.2 is added to the Business and Professions Code, to read:

4001.2. To further the purposes of Section 4001.1, and to protect the public from hazards caused by the improper management and disposal of waste drugs and devices, the

California State Board of Pharmacy shall coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes.

SEC. 2. Section 4068.1 is added to the Business and Professions Code, to read:

4068.1. A pharmacy may accept the return of home-generated pharmaceutical waste, as defined in Section 117769 of the Health and Safety Code, from the public.

SEC. 3. Section 4146 is added to the Business and Professions Code, to read:

4146. A pharmacy may accept the return of home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, from a person if the waste is contained in a sharps container.

SEC. 4. Section 117642 is added to the Health and Safety Code, to read:

117642. "Common carrier" means a person or company that hauls for hire goods, including, but not limited to, pharmaceutical waste or home-generated pharmaceutical waste. Home-generated pharmaceutical waste must have been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 5. Section 117669 is added to the Health and Safety Code, to read:

117669. "Home-generated pharmaceutical waste" means prescribed and over-the-counter drugs derived from a household.

SEC. 6. Section 117700 of the Health and Safety Code is amended to read:

117700. Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.

(d) Waste ~~which~~ *that* is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671, *and home-generated pharmaceutical waste, as defined in Section 117669.*

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

SEC. 7. Section 117748 is added to the Health and Safety Code, to read:

117748. "Pharmaceutical waste" means any pharmaceutical, prescription, or over-the-counter human or veterinary drug, including, but not limited to, a drug, as defined in Section 109925, or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(g)(1)) that meets any of the following requirements:

(a) The drug may no longer be sold or dispensed because it has expired.

(b) The drug can no longer be used for its intended purpose.

(c) The drug has been discarded.

(d) The drug has been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 8. Section 117904.5 is added to the Health and Safety Code, to read:

117904.5. (a) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a location as a point of consolidation for the collection of home-generated pharmaceutical waste. These locations may include, but are not limited to, pharmacies, heath care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, or government offices.

(b) A consolidation location approved pursuant to this section shall be known as a home-generated pharmaceutical waste consolidation point.

(c) A home-generated pharmaceutical waste consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275) of Part 14 of Division 4, to the permit

requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated pharmaceutical waste pursuant to this section.

(d) A home-generated pharmaceutical waste consolidation point shall comply with all of the following requirements:

(1) It shall be approved by the enforcement agency for this purpose.

(2) The home-generated pharmaceutical waste collected and consolidated at the facility shall be collected and contained in a leak-resistant container and placed in a secure area that does not allow the waste to be accessed or salvaged by unauthorized persons.

(3) Containers ready for disposal shall not be held for more than 90 days without the written approval of the enforcement agency.

(e) An operator of a home-generated pharmaceutical waste consolidation point that is approved pursuant to this section shall not be considered a generator of that waste.

(f) The end disposal facility that treats the home-generated pharmaceutical waste shall maintain the tracking documents required by Section 118040 or 118041, as applicable, and Section 118165 with regard to the pharmaceutical waste.

(g) Nothing in this section shall exempt any person from any federal or state law governing pharmaceuticals.

SEC. 9. Section 117935 of the Health and Safety Code is amended to read:

117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, ~~or~~ the name of the registered hazardous waste hauler

used by the generator to have untreated medical waste removed for treatment and disposal, *and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal.*

(g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.

(h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.

(i) A statement certifying that the information provided is complete and accurate.

SEC. 10. Section 117945 of the Health and Safety Code is amended to read:

117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, and the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, *or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031.* The small quantity generator shall maintain these records for not less than two years.

SEC. 11. Section 117960 of the Health and Safety Code is amended to read:

117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.

(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, *or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031.*

(g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe, if applicable.

(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.

(i) An emergency action plan complying with regulations adopted by the department.

(j) A statement certifying that the information provided is complete and accurate.

SEC. 12. Section 118000 of the Health and Safety Code is amended to read:

118000. (a) Except as otherwise exempted pursuant to Section 118030 *or 118031*, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 *or small quantity generators or common carriers transporting home-generated pharmaceutical waste pursuant to Section 118031*, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.

(c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.

(d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

(f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

SEC. 13. Section 118031 is added to the Health and Safety Code, to read:

118031. Pharmaceutical waste may be shipped by a common carrier if the generator or home-generated pharmaceutical waste consolidation point meets the following requirements:

(a) The facility shall maintain documentation as required in Sections 118040 and 118041.

(b) The waste products are transported to any of the following:

(1) A medical waste facility.

(2) A hazardous waste facility.

(3) A reverse distributor, with the final destination of a medical or hazardous waste facility.

SEC. 14. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, *pharmaceutical waste or home-generated pharmaceutical waste consolidated by a home-generated pharmaceutical waste consolidation point approved pursuant to Section 117904.5, or home-generated pharmaceutical waste transported pursuant to Section 118031,* a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.

(2) The type and quantity of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his

or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

(f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.

SEC. 15. Section 118041 is added to the Health and Safety Code, to read:

118041. (a) A person transporting pharmaceutical waste shall maintain a completed tracking document of all pharmaceutical waste removed for treatment or disposal. A copy of the tracking document shall be included with the container holding the pharmaceutical waste.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, and telephone number of the generator.

(2) Specific information indicating that pharmaceutical waste is being transported.

(3) The name, address, and telephone number of the person transporting the waste.

(4) The name, address, telephone number, and permit number of the permitted treatment facility or transfer station to which the pharmaceutical waste is being sent.

(5) The date that the pharmaceutical waste was collected or removed from the generator or home-generated pharmaceutical waste consolidation point.

(c) A person tracking pharmaceutical waste shall have a tracking document for the waste in his or her possession while transporting the waste. The tracking document shall be shown, upon demand, to any enforcement agency personnel or officer of the Department of the California Highway Patrol.

(d) A medical waste treatment facility and transfer station shall date and sign a copy of the tracking document upon receipt, periodically provide data in a format determined by the department, and shall maintain a copy of the tracking document for three years.

(e) This section does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal of the pharmaceutical waste over a period of time, if the form or log is maintained in the files of the parent organization or other health care facility that receives the waste.

(f) Pharmaceutical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state, or if the waste is crossing an international border, the home-generated pharmaceutical waste shall be treated pursuant to Section 118222 prior to being transported out of state.

SEC. 16. Section 118147 of the Health and Safety Code is amended to read:

118147. Notwithstanding any other provision of this chapter, a registered medical waste generator, which is a facility specified in subdivisions (a) and (b) of Section 117705, may accept home-generated sharps waste *and home-generated pharmaceutical waste*, to be consolidated with the facility's medical waste stream, subject to all of the following conditions:

(a) The generator of the *home-generated* sharps waste *or home-generated pharmaceutical waste*, a member of the generator's family, or a person authorized by the enforcement agency transports the sharps waste *or pharmaceutical waste* to the medical waste generator's facility.

(2) Notwithstanding paragraph (1), the total amount of grants made by the board pursuant to this section may exceed three million dollars ($3,000,000) but shall not exceed six million dollars ($6,000,000), in any one fiscal year, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

SEC. 19. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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